Journal of the American Society of Nephrology

VOLUME 9
ISSUE 11
NOVEMBER 1998
In hypertension or angina every Tom, Dick, needs effective control...
Consider NORVASC—the #1 branded agent for hypertension and/or angina¹*

Easy to start with and stay with²,³

Effective in all stages of hypertension, including severe hypertension⁴

Safely used in patients with common concomitant conditions, such as diabetes, COPD, and abnormal lipids⁴

No known drug interactions

No clinically significant effect on cardiac conduction or heart rate

In clinical trials, the most common side effects versus placebo were

- edema (8.3% vs 2.4%)
- headache (7.3% vs 7.8%)
- fatigue (4.5% vs 2.8%)
- dizziness (3.2% vs 3.4%)

Once-Daily NORVASC (amlodipine besylate)

*Among branded cardiovascular agents indicated for hypertension and/or angina.*

Please see brief summary of prescribing information on next page.
In hypertension or angina...

Convenient once-daily dosing

The usual starting dose is 5 mg in hypertension or angina.
— In hypertension, small, fragile, or elderly individuals or patients with hepatic insufficiency may be started on 2.5 mg once daily.

Titration can proceed to 10 mg
— Most angina patients will require 10 mg

Can be taken with or without food

An excellent side-effect profile

<table>
<thead>
<tr>
<th>DOSE-RELATED SIDE EFFECTS</th>
<th>NORVASC®</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edema</td>
<td>3.0</td>
<td>10.6</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.4</td>
<td>3.4</td>
</tr>
<tr>
<td>Flushing</td>
<td>1.4</td>
<td>2.6</td>
</tr>
<tr>
<td>Palpitation</td>
<td>1.4</td>
<td>4.5</td>
</tr>
</tbody>
</table>

Brief Summary
NORVASC® (amlodipine besylate) Tablets
For Oral Use

CONTRAINDICATIONS: NORVASC® is contraindicated in patients with known sensitivity to amlodipine.

WARNINGS: Increased Angina and/or Myocardial Ischemia: Rarely, patients particularly those with severe obstructive coronary artery disease, have developed documented increased frequency, duration and/or severity of angina or acute myocardial ischemia on starting calcium channel blocker therapy or at the time of dose increase. The mechanism of this effect has not been elucidated.

PRECAUTIONS: General: Since the vasodilatation produced by NORVASC® is gradual, acute hypotension has rarely been reported after oral administration of NORVASC®. Nonetheless, caution should be exercised when administering NORVASC® as with any other peripheral vasodilator particularly in patients with severe aortic stenosis. Use in Patients with Congestive Heart Failure: In general, cardiac channel blockers should be used with caution in patients with heart failure. NORVASC® (5-10 mg per day) has been taken in a placebo-controlled trial of 1150 patients with NYHA Class IV heart failure on stable doses of ACE inhibitors, digitals and diuretics. Follow-up was at least 6 months, with a mean of about 14 months. There was no overall adverse event on survival or cardiac morbidity (as defined by hospitalization for refractory heart failure, acute myocardial infarction or death). No patients died during NORVASC® treatment. NORVASC® has been compared to placebo in four 8-12 week studies of patients with NYHA Class III heart failure, involving over 1200 patients. In these studies, there was no evidence of worsened heart failure based on measures of exercise tolerance, NYHA classification, or other endpoints. Use in Patients with Renal Insufficiency: Since NORVASC® is extensively metabolized by the liver and the plasma elimination half-life of 14-20 hours is not appreciably changed in patients with impaired renal function. NORVASC® should be initiated with a dose of 2.5 mg taken once daily. The dosage should be increased by 2.5 mg weekly. The maximum dose of 10 mg/day may be reached by the sixteenth week. Use in Patients with Hepatic Insufficiency: Since NORVASC® is not known to be significantly metabolized by the liver, no dosage adjustment is recommended in patients with hepatic insufficiency.

— Drug/Laboratory Test Interactions: None known.

Cardiogenesis, Biogenesis, Impairment of Fertility: Rate and time with treated with amlodipine in the diet for two years, at concentrations calculated to provide daily dosage levels of 0.125, 2.5 mg/kg/day showed no evidence of carcinogenicity. The highest dose (for mice, rats and rabbits) the maximum recommended dose (clinical dose of 10 mg/m²/day), was close to the maximum tolerated dose for mice but not rats. Mutagenicity studies revealed no drug-related effects at either the gene or chromosomal levels. There was no effect on the fertility of rats treated with amlodipine (total for 64 days and females 14 days prior to mating) at doses up to 10 mg/m²/day (6 times the maximum recommended human dose of 10 mg/m²/day, based on body surface area). Pregnancy Category C. No evidence of teratogenicity or embryotoxicity was found in rats or rabbits when females were treated orally with 10 mg/kg amlodipine (respectively 2-3 times and 3-4 times the maximum recommended human dose of 10 mg/m²/day, based on body surface area). Maternal toxicity (e.g., increased fetal resorptions was observed at 20 mg/kg/day). All pregnant rats were treated orally with 10 mg/kg amlodipine (respectively 12 and 7 times the maximum recommended human dose of 10 mg/m²/day, based on body surface area) during three respective periods of major organ development. The mean maternal weight gain was significantly decreased (by about 100%) and the number of intrauterine deaths was significantly increased (about 5-fold) in rats administered 120 mg/kg amlodipine for 14 days before mating and throughout gestation and lactation. Amlodipine has been shown to prolong both the gestation period and the duration of labor in rats. There are no adequate and well-controlled studies in pregnant women. Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing Mothers: It is not known whether amlodipine is excreted in human milk. In the absence of this information, it is recommended that nursing be discontinued while NORVASC® is administered. Pediatric Use: Safety and effectiveness of NORVASC® in children have not been established.

Adverse Reactions: NORVASC® has been evaluated for safety in more than 11,000 patients in U.S. and foreign clinical trials. In general, treatment with NORVASC® was well-tolerated at doses up to 10 mg/day. Most adverse reactions reported during therapy with NORVASC® were mild or moderate in severity. In controlled clinical trials directly comparing NORVASC® (10-170 mg) in doses up to 10 mg to placebo (N=1250), discontinuation of NORVASC® due to adverse reactions was required in only about 1.5% of patients and was not significantly different from placebo (about 1%). The most common side-effects are headache and edema. The incidence of 5% or greater incidence of side-effects by treatment regimen and grading is as follows: edema (10% in 2.5 mg, 3% in 5 mg, and 10% in 10 mg compared with placebo), dizziness (6% in 2.5 mg, 3% in 5 mg, and 10% in 10 mg compared with placebo), flushing (3% in 2.5 mg, 5% in 5 mg, and 10% in 10 mg compared with placebo), palpitation (7% in 2.5 mg, 1% in 5 mg, and 10% in 10 mg compared with placebo), and somnolence (1% compared with placebo). Other adverse experiences which were not clearly dose related but which were reported with an incidence greater than 1% in placebo-controlled clinical trials include the following: headache (7.3% with 7.8% placebo), fatigue (4.5% vs. 2.2% placebo), nausea (2.2% compared with 1.8% placebo), abdominal pain (1.6% compared with 0.3% placebo), and somnolence (1% compared with placebo) for several adverse experiences, it is not possible to attribute any meaningful differences to treatment with norvasc® or placebo due to small patient numbers and the complex nature of angina and its management. Summary of clinical adverse experiences: The most common adverse experiences were headache, flushing, edema, palpitation, dyspnea, and asthenia.
Announcing a new partnership between the Journal of the American Society of Nephrology and UpToDate®, Inc.

The Journal of the American Society of Nephrology is the premier source for the latest scientific developments in nephrology. This role will be further enhanced by an exciting new information service provided by the Journal and UpToDate®, Inc. beginning in January 1999.

If you are a subscriber to the Journal of the American Society of Nephrology and have access to the Internet, this new free information service will provide you with in-depth analyses, state-of-the-art summaries and pertinent literature citations on selected clinical subjects all compiled by leading experts in nephrology.

Come to the JASN and UpToDate®, Inc. booths at the ASN annual meeting in Philadelphia, October 25–28, 1998 to see a demonstration of this new and innovative way to obtain the latest information in the science and clinical practice of nephrology.

Keep watching for more information about this exciting new service for ASN members and Journal subscribers in future issues!
ASN MAILING LIST INFORMATION

Size and Description: The ASN mailing list consists of approximately 6,100 members in the U.S., Canada and abroad. Approximately 5,000 of these members reside in the United States. You may request rental of any or all portions of the list.

Costs: Label costs are $100 per thousand or any portion of a thousand with a minimum order of $300. Advance payment is required and the price includes shipping via UPS ground. The ASN will be happy to ship your labels via Federal Express if you include a charge number with your order. Orders shipped outside the U.S. will be subject to an additional delivery charge.

Delivery Time: Approximately 7-10 days from approval of your order. (Allow longer for orders outside the U.S.)

Sorts: Labels are available in alphabetical or zip code order on Cheshire paper. Pressure sensitive labels are available at an additional cost of $5.00 per thousand.

Organizations that wish to rent the ASN mailing list must submit a sample of the distribution material and sign the following paragraph. Submit these documents to the ASN office to begin the rental approval process. Please be sure to include your mailing address (with a street address) with the request.

I, ________________________________________, representing ______________________, request permission to rent the ASN mailing list. I understand that if my request is approved, I may use the mailing list to send only one mailing of the material that has been approved. I understand that making copies of the list or entering the list into my own computer is a violation of the rental agreement and the ASN copyright, and I agree not to replicate the list in any way or use it to create my own list. If I should use the list again without authorization, I understand that I will be liable for an additional rental fee and subject to legal action.

________________________________________
Signature

________________________________________
Title

____________________________
Date

Please circle following:

Pressure Sensitive Zip-code Order Entire List
Cheshire Alphabethical Partial List: (Describe)
In combination therapy

Roche brings the first humanized monoclonal antibody to renal transplantation.
ZENAPAX® (Daclizumab), the first humanized IL-2R–specific monoclonal antibody, prevents acute renal allograft rejection as part of an immunosuppressive regimen.

- Binds with high affinity to the Tac subunit which is expressed on activated but not resting lymphocytes.
- A unique, bioengineered monoclonal antibody therapy, 90% human IgG sequences and 10% murine sequences, that mirrors human IgG.
- Inhibits IL-2–mediated activation and proliferation of T cells, a critical pathway in the cellular immune response involved in allograft rejection.

**WARNING:** Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should prescribe ZENAPAX® (Daclizumab). The physician responsible for ZENAPAX administration should have complete information requisite for the follow-up of the patient. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources.

Patients on immunosuppressive therapy are at increased risk for developing lymphoproliferative disorders and opportunistic infections and should be monitored accordingly.

ZENAPAX is contraindicated in patients with known hypersensitivity to Daclizumab or to any components of this product. Anaphylactoid reactions have not been observed following ZENAPAX administration, but can occur following the administration of proteins.

Please see brief summary of product information for ZENAPAX and for CellCept® (mycophenolate mofetil), which include contraindications, warnings, precautions and adverse events, on back pages of this advertisement.

*Data from two randomized, double-blind, multicenter trials that compared a dose of 1.0 mg/kg of ZENAPAX with placebo when each was administered as part of an immunosuppressive regimen with triple therapy (cyclosporine + corticosteroids + AZA) or double therapy (cyclosporine + corticosteroids).
ZENAPAX increases efficacy without an increase in serious side effects.

- Significantly reduces acute renal allograft rejection episodes when added to triple and double immunosuppressive protocols.*
- Associated with significantly better patient survival at 1 year in the double-therapy regimen. No significant difference in patient survival when added to a triple-therapy regimen.
- A retrospective analysis of the combined endpoint of patient survival, graft survival and acute rejection in triple- and double-therapy regimens at 1 year suggests a better outcome for patients receiving ZENAPAX as part of their immunosuppressive regimen.
- No increases in lymphomas or overall incidence of infectious episodes were observed.
- The most frequently reported adverse events were GI disorders (e.g., constipation, nausea, diarrhea, vomiting), which were reported with equal frequency in the ZENAPAX group (67% [226/336]) and placebo group (68% [193/293]). The overall incidence of infectious episodes was not higher in patients treated with ZENAPAX compared with patients receiving placebo. However, cellulitis and wound infections occurred in 8.4% (24/286) of patients treated with ZENAPAX and 4.1% (11/268) receiving placebo.
- Well tolerated with CellCept® (mycophenolate mofetil), cyclosporine and corticosteroids.

* Well tolerated with CellCept® (mycophenolate mofetil), cyclosporine and corticosteroids.

Immunosuppression with a human touch.
**ZENAPAX**

**Indication:**
ZENAPAX* (Daclizumab) is indicated for the prophylaxis of acute organ rejection in patients receiving renal transplants. It is used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids.

**Contraindications:** ZENAPAX is contraindicated in patients with known hypersensitivity to Daclizumab or any components of this product.

**Warnings:**

- **See Boxed Warning.**
- ZENAPAX should be administered under qualified medical supervision. Patients should be monitored for the potential benefits of therapy and the risks associated with administration of immunosuppressive therapy.
- The incidence of lymphoproliferative disorders and opportunistic infections, in the limited clinical trial experience, was no higher in ZENAPAX-treated patients compared with placebo-treated patients. However, the incidence of immunogenicity was increased in ZENAPAX-treated patients.
- ZENAPAX is not immunogenic when administered concomitantly with cyclosporine.
- ZENAPAX should be administered to patients with normal renal function. During ZENAPAX therapy, serum creatinine levels should be monitored at regular intervals.
- ZENAPAX is not recommended for patients with a history of severe adverse events or for patients with known risk factors for severe adverse events.

**Adverse Reactions:**

- Hematopoietic: Agranulocytosis, neutropenia, monocytopenia, eosinophilia, and thrombocytopenia were observed in ZENAPAX-treated patients. The incidence of immune thrombocytopenia purpura (ITP) was increased in ZENAPAX-treated patients.
- Gastrointestinal: Nausea, vomiting, diarrhea, and abdominal pain were observed in ZENAPAX-treated patients.
- Hepatobiliary: Liver function tests were abnormal in ZENAPAX-treated patients.
- Cardiovascular: Hypertension and myocardial infarction were observed in ZENAPAX-treated patients.
- Respiratory: Coughing, wheezing, and dyspnea were observed in ZENAPAX-treated patients.
- Central and Peripheral Nervous System: Headache, dizziness, and tinnitus were observed in ZENAPAX-treated patients.
- Skin: Pruritus, rash, and urticaria were observed in ZENAPAX-treated patients.
- Local and Systemic: Injection site reactions were observed in ZENAPAX-treated patients.

**Pregnancy and Lactation:**

- Pregnancy Category C: Animal reproduction studies have not been conducted with ZENAPAX.

**General Information:**

- ZENAPAX is a humanized monoclonal IgG1 kappa immunoglobulin. It is administered as a 2 mg/kg subcutaneous injection every 2 weeks. It is not considered a potentiated drug and is not recommended for use with potentiated drugs.

**Pharmacology:**

- ZENAPAX binds to the IL-2 receptor (CD25) on activated T cells and inhibits the proliferative response of T cells to IL-2, thus reducing the immune response to organ transplantation.

**Dosage and Administration:**

- ZENAPAX is administered as a subcutaneous injection every 2 weeks. The recommended dose is 2 mg/kg of body weight.

**Storability:**

- ZENAPAX is stored at 2-8°C (36-46°F) and should be protected from freezing.

**Clinical Trials:**

- ZENAPAX was studied in 629 patients receiving renal allografts of whom 336 received ZENAPAX and 293 received placebo. All patients received cyclosporine and corticosteroids.

**Indications:**

- ZENAPAX was studied in three randomized controlled clinical trials, each with a different population of patients. In one trial, ZENAPAX-treated patients had a lower incidence of acute rejection than placebo-treated patients. In another trial, ZENAPAX-treated patients had a lower incidence of acute rejection than placebo-treated patients but had a higher incidence of delayed-onset rejection. In a third trial, ZENAPAX-treated patients had a lower incidence of acute rejection than placebo-treated patients but had a higher incidence of delayed-onset rejection.

**Conclusions:**

- ZENAPAX is effective in reducing the incidence of acute rejection in patients receiving renal transplants. It is recommended for use in patients with a history of acute rejection or in patients with a high risk of acute rejection.

**References:**

- Roche Laboratories Inc.

340 Kingsland Street
Nutley, New Jersey 07110-1199

Issued: December 1997

Printed in U.S.A.

17-090-072-003-078
The document contains information about cellcept (mycophenolate mofetil) capsules and tablets. It discusses adverse reactions, therapeutic uses, and precautions. Here is a summary of the key points:

**Adverse Reactions**
- Cellcept can cause an increased incidence of gastrointestinal adverse events. Patients may experience nausea, vomiting, diarrhea, anorexia, constipation, and abdominal pain.
- The most common adverse reactions include nausea, vomiting, diarrhea, anorexia, and abdominal pain.
- Other less common reactions include fever, chest pain, thrombocytopenia, and rash.
- Cellcept may cause an increased incidence of infections, such as upper respiratory infections, urinary tract infections, and pneumonia.

**Precautions**
- Cellcept should not be used in patients with active or recent infection, as it may worsen the infection.
- Cellcept should not be used in patients with a history of severe hepatic impairment.
- Cellcept should be used with caution in patients with a history of severe renal impairment.
- Cellcept should be used with caution in patients with a history of severe cardiac impairment.

**Therapeutic Uses**
- Cellcept is used to prevent organ rejection in patients receiving organ transplants.
- Cellcept is used to treat certain intractable conditions, such as severe rheumatoid arthritis.

**Pharmacokinetics**
- Cellcept is absorbed rapidly after oral administration. The mean AUC and mean maximum plasma concentration (C_max) were greater than those observed after oral administration of mofetil.
- Cellcept is extensively metabolized in the liver to form pharmacologically active metabolites, including mycophenolic acid (MPA) and 3MP.

**Interactions**
- Cellcept may interact with other drugs, such as cyclosporine, azathioprine, and methotrexate, increasing the risk of adverse effects.
- Cellcept may increase the risk of bleeding when used with warfarin or other anticoagulants.

**Dosing**
- Cellcept is usually administered orally, once or twice daily, depending on the patient's condition.

**Side Effects**
- Common side effects include nausea, vomiting, diarrhea, and abdominal pain.
- Less common side effects include fever, chest pain, thrombocytopenia, and rash.

**Contraindications**
- Cellcept should not be used in patients with a history of severe hepatic impairment.
- Cellcept should not be used in patients with a history of severe renal impairment.
- Cellcept should not be used in patients with a history of severe cardiac impairment.

This summary is based on the information provided in the document. For more detailed information, please refer to the document itself.
Asthma
Pleural
Dyspnea
Constipation
SGOT
Peripheral
Cardiovascular
Hypotension
Hypertension
Urinary
Thrombocytopenia
Pain
In
Lymphatic
Otsi
10.7
19.0
In
16.6
21.0
Gastrointestinal:
Hepatitis
portal hypertension
Metastatic and lymphatic
alkaline phosphatase increased,
dehydration, hyperviscosity, hypocalcemia,
hyperglycemia,
hyperuricemia,
hyperalbuminemia,
other agents:
volatile organic compounds,
ventricular extrasystole,
congestive heart failure,
progressive tachycardia,
ventricular tachycardia,
aortic stenosis,
hypercholesterolemia,
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Application for Active and Corresponding Membership

Last Name ____________________________ First Name ____________________________ Middle Initial(s) ____________________________

Preferred Mailing Address

City ____________________________ State/Province ____________________________ ZIP/Postal Code ____________________________ Country ____________________________

Business Address (If not listed above)

City ____________________________ State/Province ____________________________ ZIP/Postal Code ____________________________ Country ____________________________

Business Telephone ____________________________ Business Fax ____________________________ E-Mail Address ____________________________

Date of Birth ____________________________ Sex ____________________________ Country of Citizenship ____________________________

If you reside in the United States, but are not a U.S. citizen, please provide visa status.
(Individuals residing in the United States with temporary visa status will apply for corresponding membership).

Academic Appointment: ☐ Full Time ☐ Part Time ☐ None

Primary Professional Interest (e.g., adult nephrology, pediatric nephrology, pathology, urology, physiology, etc.)

Primary Institutional Affiliation (e.g., medical school-faculty/clinical dept., medical school-faculty/research dept., hospital-staff/clinical staff, private practice, armed forces or other federal services, etc.)

Present Hospital/University Appointments (titles and departmental affiliations)

__________

Please indicate the amount of time spent on the following activities. Your total should amount to 100 percent.

Clinical ____________ Research ____________ Teaching ____________ Administration ____________ Other ____________

Professional Education and Training (To qualify for active and corresponding membership, you must have an M.D., Ph.D., or equivalent such as D.O., D.V.M., F.R.C.P., M.B.B.S., Pharm.D., etc.)

Institutional Name/Address ____________________________ Degree ____________________________ Dates ____________________________

For office use only:

ID# ____________________________ Date entered: ____________________________ Check#: ____________________________ Check name: ____________________________
Training in nephrology (Give inclusive dates for residences, fellowships, other relevant postgraduate education).

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<thead>
<tr>
<th>Institution Name/Address</th>
<th>Position</th>
<th>Preceptor(s)</th>
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List your five most significant publications.

________________________________________

________________________________________

________________________________________

________________________________________

Describe your clinical experience as a specialist and consultant in kidney disease and related conditions that would provide basis for qualification of membership.

________________________________________

________________________________________

________________________________________

List other societies to which you belong.

________________________________________

________________________________________

________________________________________

Provide names and addresses of three persons from whom letters of reference may be requested if needed.

________________________________________

________________________________________

________________________________________

Please return your completed application with the first year's dues (see below) payable to the ASN in U.S. funds.

$140 — Active Membership for residents of North or Central America*

$155 — Corresponding Membership for those who meet the qualifications for Active Membership, but are not residents of North or Central America. Corresponding members will receive all Society mailings and member discounts, but do not have the right to vote or hold office.

*Active Members temporarily living outside North America must submit a $15 postal surcharge.

If you would like to pay by VISA or MasterCard, please list the cardholder's name, number and expiration date below:

☐ VISA       ☐ MasterCard

Cardholder's Name (please print or type) ____________________________ Signature ____________________________

Card Number ____________________________ Expiration Date ____________________________
There is no significant difference in the relative risk of mortality between modified cellulose and synthetic membranes."

HAKIM, R. ET AL


<table>
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<tr>
<th>MEMBRANE</th>
<th>ADJUSTED FOR Kt/V&lt;sup&gt;b&lt;/sup&gt;</th>
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<tr>
<td>Cellulose</td>
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<tr>
<td>Modified Cellulose</td>
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</tr>
<tr>
<td>Synthetic</td>
<td>0.75&lt;sup&gt;d&lt;/sup&gt;</td>
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<sup>b</sup> After adjustment for all other risk factors and co-morbid conditions
<sup>d</sup> P<0.002

Modified Cellulose membranes include: Cellulose Triacetate (Baxter <sup>CTT</sup>™ dialyzer) and Cellulose Acetate (Baxter <sup>CA-HP™</sup> Dialyzer)

To learn more about the Baxter <sup>CT™</sup> High Flux and <sup>CA-HP™</sup> High Performance dialyzers contact your Baxter Account Executive at 1-888-RENALHELP (1-888-736-2543), option 4.
American Society of Nephrology

1998 Renal Week • October 23-31, 1998


ASN Postgraduate Education Courses
(eight concurrent 2-day PGE courses)
PENNSYLVANIA CONVENTION CENTER • PHILADELPHIA, PA

The Principles and Practice of Hemodialysis: Reviews, Updates and Demonstrations
Course Chair:
Steve J. Schwab
Durham, NC

Epidemiology: The Principles and Application to Clinical Nephrology
Course Chair:
Andrew S. Levey
Boston, MA

Intensive Care Nephrology: Intensive Review and Case Discussions
(co-sponsored by the American College of Chest Physicians)
Course Chair:
Paul M. Palevsky
Pittsburgh, PA

Interventional Nephrology: Expanding our Procedural Domain
Course Chair:
Gerald A. Beathard
Austin, TX

Introduction to Molecular Biology: Lectures and Clinically Relevant Workshops
Course Chair:
Steven C. Hebert
Nashville, TN

Practical Computing for Nephrologists: Maximizing Computer Techniques in Education & Practice
Course Chairs:
Jesse M. Goldman
Philadelphia, PA
Jerry Yee
Detroit, MI

Renal Transplantation: From Bench to Bedside
(co-sponsored by the American Society of Transplant Physicians)
Course Chairs:
Mohamed H. Sayegh
Boston, MA
Laurence A. Turka
Philadelphia, PA

Basic Renal Pathology: From Bedside to Bench
(co-sponsored by the Renal Pathology Society)
Course Chair:
Agnes B. Fogo
Nashville, TN

Day 2: October 24, 1998

ASN Innovative Science Conference
PENNSYLVANIA CONVENTION CENTER • PHILADELPHIA, PA

Targeting of Proteins, Organelles and Cells
Conference Chairs:
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Days 3-6: October 25-28, 1998

ASN 31st Annual Meeting & Scientific Exposition
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Symposia: Basic Science Symposia; Clinical Science Symposia, and; Clinical Nephrology Symposia (formerly known as Short Courses)
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Scientific Exposition


ASN Basic Science/ISN Forefronts Conference
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Ion Channelopathies: Hereditary Dysfunction of Ion Channels
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Join the ASN for this premier week in nephrology.
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Just because you don't see carnitine deficiency doesn't mean it's not there.

Carnitine plays a vital role in energy production. Typically, 75% of a patient's carnitine needs are met through dietary intake. And healthy patients depend on proper liver and kidney function to maintain adequate carnitine status. Carnitine functions by binding with fatty acids so they can be transported into the mitochondria for energy production and also binds with metabolic waste products so they can be transported out of the body.

Carnitine deficiency is hard to detect and often overlooked. Patients who exhibit findings consistent with carnitine deficiency should be evaluated for treatment with Carnitor®.

Clinical findings associated with carnitine deficiency may be as subtle as any of the following:
- cardiomyopathy
- muscle weakness
- lethargy
- poor muscle tone
- seizures
- low levels of activity
- developmental delay
- slow growth

Carnitor® is the only treatment for carnitine deficiency.

For Carnitor® Medicare reimbursement assistance, call 1-800-490-3262.

For any other questions, call 1-800-447-0169.

Please see adjacent brief prescribing information.
**Carnitine Deficiency**

**Clinical Findings Associated with Carnitine Deficiency:**
- cardiomyopathy
- muscle weakness
- lethargy
- poor muscle tone
- seizures
- low levels of activity
- developmental delay
- slow growth

**Conditions Associated with Increased Risk for Developing Carnitine Deficiency:**
- fatty acid oxidation defects
- mitochondrial myopathy
- dialysis
- premature birth
- administration of carnitine- free TPN
- treatment for HIV—especially administration of zidovudine (AZT)
- administration of valproic acid
- administration of pivalate derivatives
- administration of emetine
- administration of sodium benzoate

**CARNITOR®** (Levocarnitine) Tablets and Oral Solution are indicated in the treatment of primary systemic carnitine deficiency. In the reported cases, the clinical presentation consisted of recurrent episodes of Raye-

**Indications and usage**

CARNITOR® (Levocarnitine) Tablets and Oral Solution are indicated in the treatment of primary systemic carnitine deficiency. In the reported cases, the clinical presentation consisted of recurrent episodes of Raye-

**Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Pediatric use**

See Dosage and administration.

**Adverse reactions**

CARNITOR® (Levocarnitine) Oral Solution and Tablets. Various mild gastrointestinal complaints have been reported during the long-term administration of oral L- or D,L-carnitine; these include transient nausea and vomiting, abdominal cramps, and diarrhea. Mild myasthenia has been described only in uramic patients receiving D,L-carnitine. Gastrointestinal adverse reactions with CARNITOR® (Levocarnitine) Oral Solution dissolved in liquids might be avoided by a slow consumption of the solution or by a greater dilution. Decreasing the dosage often diminishes or eliminates drug-related patient body odor or gastrointestinal symptoms when present. Tolerance should be monitored very closely during the first week of administration, and after any dosage increases.

Seizures have been reported to occur in patients with or without pre-

Seizures have been reported to occur in patients with or without pre-

**References**

10. Rebouche C: Quantitative estimation of absorption and degra-

**Pharmaceuticals, Inc.**

800 S. Frederick Avenue • Suite 300 • Gaithersburg, MD 20877
TEL: (800) 447-6769
FAX: (301) 948-3194
EMAIL: info@si@nattau.com
WEB: www.sigma-tau.com
Introducing antibody induction made simple.
Warning: Only physicians experienced in immunosuppression therapy and management of organ transplantation patients should prescribe SIMULECT® (basiliximab). The physician responsible for SIMULECT administration should have complete information requisite for the follow-up of the patient. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources.

While the incidence of lymphoproliferative disorders and opportunistic infection in the controlled clinical trials was no higher in SIMULECT-treated patients than in patients treated with placebo, patients on immunosuppressive therapy are at increased risk for developing lymphoproliferative disorders and opportunistic infections and should be monitored accordingly.

SIMULECT is contraindicated in patients with known hypersensitivity to basiliximab or any other component of the formulation.
Introducing SIMULECT® ( basiliximab ) — Now Two Doses Complete Antibody Induction
New SIMULECT, when used as part of an immunosuppressive regimen that includes Neoral**
(cyclosporine for microemulsion) + corticosteroids, lowers acute rejection and maintains 1-year graft
survival—with just two 20-mg doses.† Chimerization maintains high affinity for the IL-2 receptor, with
low immunogenicity (0.4% anti-idiotype; 1 out of 246 patients)—and offers a simple, 2-dose treatment
course.† Well tolerated compared to placebo,† SIMULECT provides antibody induction that is effective,
convenient, and simple.

SIMULECT®
(basiliximab)
Antibody induction simply delivered

*Neoral is a registered trademark of Novartis Pharmaceuticals Corporation.
† Data from two randomized, double-blind, multicenter trials of de novo renal transplant recipients, comparing
two 20-mg induction doses (at day 0 and day 4) of SIMULECT with placebo when each was administered
as part of an immunosuppressive regimen with double therapy (Neoral” + corticosteroids).

Please see brief summary of prescribing information for SIMULECT and Neoral, including contraindications, warnings, precautions, and adverse
events, on following pages.

©1998 Novartis  Printed in U.S.A.  8/98  CSIM-1002  Printed on Recycled Paper
Simulect® (basiliximab)  
For Injection  
Rx only

BRIEF SUMMARY: Please see package insert for full prescribing information.

WARNING

Only physicians experienced in immunosuppression therapy and management of organ transplantation patients should prescribe Simulect® (basiliximab). The physician responsible for Simulect® administration should have complete information required for the follow-up of the patient. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources.

INDICATIONS AND USAGE

Simulect® (basiliximab) is indicated for the prophylaxis of acute organ rejection in patients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine and corticosteroids.

CONTRAINDICATIONS

Simulect® (basiliximab) is contraindicated in patients with known hypersensitivity to basiliximab or any other component of the formulation. See composition of Simulect® under DESCRIPTION in the full prescribing information.

WARNINGS: See Boxed WARNING.

General

Simulect® (basiliximab) should be administered under qualified medical supervision. Patients should be informed of the potential benefits of therapy and the risks associated with administration of immunosuppressive therapy. Anaphylactoid reactions following the administration of Simulect® have not been observed but can occur following the administration of proteins. Medications for the treatment of severe hypersensitivity reactions should be available for immediate use.

While neither the incidence of lymphoproliferative disorders nor opportunistic infections was higher in Simulect®-treated patients than in placebo-treated patients, patients on immunosuppressive therapy are at increased risk for developing these complications and should be monitored accordingly.

PRECAUTIONS

General

It is not known whether Simulect® (basiliximab) use will have a long-term effect on the ability of the immune system to respond to antigens first encountered during Simulect®-induced immunosuppression.

Re-administration of Simulect® after an initial course of therapy has not been studied in humans. The potential risks of such re-administration, specifically those associated with immunosuppression and/or the occurrence of anaphylaxis/anaphylactoid reactions, are not known.

Immunogenicity

Of renal transplantation patients treated with Simulect® (basiliximab) and tested for anti-idiotypic antibodies, 1/246 developed an anti-idiotypic antibody response, with no deleterious clinical effect upon the patient. In the US study, the incidence of human anti-murine antibody (HAMA) in renal transplantation patients treated with Simulect® was 2/138 in patients not exposed to muromonab-CD3 and 4/34 in patients who subsequently received muromonab-CD3. The available clinical data on the use of muromonab-CD3 in patients previously treated with Simulect® suggest that subsequent use of muromonab-CD3 or other murine anti-lymphocytic antibody preparations is not precluded.

Drug Interactions

No formal drug-drug interaction studies have been conducted. The following medications have been administered in clinical trials with Simulect® (basiliximab) with no incremental increase in adverse reactions: ATG/ALG, azathioprine, corticosteroids, cyclosporine, mycophenolate mofetil, and muromonab-CD3.

Carcinogenesis, Mutagenesis and Impairment of Fertility

No mutagenic potential of Simulect® was observed in the in vitro assays with Salmonella (Ames) and V79 Chinese hamster cells. No long-term or fertility studies in laboratory animals have been performed to evaluate the potential of Simulect® to produce genocytotoxicity or female impairment, respectively.

Pregnancy Category B

There are no adequate and well-controlled studies in pregnant women. No maternal toxicology, embryotoxicity, or teratogenicity was observed in cynomolgus monkeys 100 days post coltum following dosing with basiliximab during the organogenesis period; blood levels in pregnant monkeys were 13-fold higher than those seen in human patients. Immunotoxicology studies have not been performed in the offspring. Because IgG molecules are known to cross the placental barrier, because IL-2 receptor may play an important role in development of the immune system, and because animal reproduction studies are not always predictive of human response, Simulect® should only be used in pregnant women when the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should use effective contraception before beginning Simulect® therapy, during therapy, and for 2 months after completion of Simulect® therapy.

Nursing Mothers

It is not known whether Simulect® is excreted in human milk. Because many drugs including human antibodies are excreted in human milk, and because of the potential for adverse drug reactions in the breast-fed infant, nursing should be discontinued or drug should be discontinued, taking into account the importance of the drug to the mother.

Pediatric Use

No adequate and well-controlled studies have been completed in pediatric patients. In an ongoing safety and pharmacokinetic study, pediatric patients 2-11 years of age (n=8), 12-15 years of age (n=4), median age 9.5 years were treated with Simulect® via intravenous bolus injection in addition to standard immunosuppressive agents including cyclosporine, corticosteroids, azathioprine, and mycophenolate mofetil. Preliminary results indicate that 16.7% (2/12) of patients had experienced an acute rejection episode by 3 months post-transplantation. The most frequently reported adverse events were fever and urinary tract infections (41.7% each). Overall, the adverse event profile was consistent with general clinical experience in the pediatric renal transplantation population and with the profile in the controlled adult renal transplantation trials. The available pharmacokinetic data in children and adolescents are described in CLINICAL PHARMACOLOGY AND DOSAGE AND ADMINISTRATION in the full prescribing information.

It is not known whether the immune response to vaccines, infection, and other antigenic stimuli administered or encountered during Simulect® therapy is impaired or whether such response will remain impaired after Simulect® therapy.

Geriatric Use

Controlled clinical studies of Simulect® have included a small number of patients 65 years and older (Simulect® 15; placebo 19). From the available data comparing Simulect®- and placebo-treated patients, the adverse event profile in patients ≥65 years of age is not different from patients <65 years of age and no age-related dosage adjustment is required. Caution must be used in giving immunosuppressive drugs to elderly patients.

ADVERSE REACTIONS

The incidence of adverse events for Simulect® (basiliximab) was determined in two randomized comparative double-blind trials for the prevention of renal allograft rejection. A total of 721 patients received renal allografts, of which 363 received Simulect® and 358 received placebo. All patients received concomitant cyclosporine for microemulsion and corticosteroids.

Simulect® did not appear to add to the background of adverse events seen in organ transplantation patients as a consequence of their underlying disease and the concurrent administration of immunosuppressants and other medications. Adverse events were reported by 99% of the patients in the placebo-treated group and 99% of the patients in the Simulect®-treated group. Simulect® did not increase the incidence of serious adverse events observed compared with placebo. The most frequently reported adverse events were gastrointestinal disorders, reported in 75% of Simulect®-treated patients and 73% of placebo-treated patients.

The incidence and types of adverse events were similar in Simulect®-treated and placebo-treated patients. The following adverse events occurred in ≥10% of Simulect®-treated patients: Gastrointestinal System: Nausea, vomiting, dyspepsia, moniliasis; Metabolic and Nutritional: hyperkalemia, hypokalemia, hyperglycemia, hyperuricemia, hypophosphatemia, hypocalcemia, weight increase, hypercholesterolemia, acidosis; Central and Peripheral Nervous System: headache, tremor, dizziness; Urinary System: dysuria, increased non-protein nitrogen, urinary tract infection; Body as a Whole-General: pain, peripheral edema, edema, fever, viral infection, leg edema, anxiety; Cardiovascular Disorders-General: hypertension; Respiratory System: dyspnea, upper respiratory tract infection, coughing, rhinitis, pharyngitis; Skin and Appendages: surgical wound complications, acne; Psychiatric: insomnia; Musculoskeletal System: leg pain, back pain; Red Blood Cell: anemia.

The following adverse events, not mentioned above, were reported with an incidence of ≥3% and <10% in patients treated with Simulect® in the two controlled clinical trials: Body as a Whole: accidental trauma, chest pain, increased drug level, face edema, fatigue, infection, malaise, generalized edema, rigors, sepsis; Cardiovascular: angina pectoris, cardiac failure, chest pain, abnormal heart sounds, aggravated hypertension; Hypertension; Nervous System: hypothyreosis, neuropathy, paresthesia; Endocrine: increased glucocorticoids; Gastrointestinal: enlarged abdomen, flatulence, gastrointestinal dysmotility, gastritis, gum hyperplasia, gum hyperplasia; Hematologic: decreased platelet count, iron deficiency; Other: increased ALT, hypertension, hematuria, gingival hyperplasia, gum hyperplasia, gum hyperplasia, gum hyperplasia; Heart Rate and Rhythm: arrhythmia, atrial fibrillation, tachycardia; Metabolic and Nutritional: dehydration, diabetes mellitus, fluid overload, hypercalcemia, hyperlipemia, hypoglycemia, hypoproteinemia, hypogammaglobulinemia; Musculoskeletal: arthritis, arthralgia, bone fracture, cramps, hernia, myalgia; Nervous System: paralytic ileus; Other: retroperitoneal hematoma; Skin and Appendages: cyst, herpetiform, rash, urticaria, wheal, whealing, urticaria; Vision disorders: conjunctivitis, photophobia; Reproductive Disorders, Male: impotence, genital depression; Respiratory: bronchitis, bronchospasm, abnormal chest sounds, pneumonia, pulmonary disorder, pulmonary edema, sinusitis; Skin and Appendages: cyst, herpetiform, rash, urticaria, wheal, whealing, urticaria; Cardiovascular: arrhythmia; Vision Disorders: cataract, conjunctivitis, abnormal vision.

Incidence of Malignancies: The overall incidence of malignancies among all patients in the two 12-month controlled trials was not significantly different between the Simulect® and placebo treatment groups. Overall, lymphoma/lymphoproliferative disease occurred in 1 patient (0.3%) in the Simulect® group compared with 2 patients (0.6%) in the placebo group. Other malignancies were reported among 5 patients (1.4%) in the Simulect® group compared with 7 patients (1.9%) in patients treated with placebo.

Incidence of Infections Episodess: Cytomegalovirus infection was reported in 14% of Simulect®-treated patients and 18% of placebo-treated patients. The rates of infections, serious infections, and infectious diseases were similar in the Simulect® and placebo treatment groups.

Store lyophilized Simulect® under refrigerated conditions (2°C to 8°C; 36°F to 46°F). Do not use beyond the expiration date stamped on the vial.

Distributed by:
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

US License No. 1244
May 1998 P30154901
**NEORAL® Soft Gelatin Capsules** (cyclosporine capsules for microemulsion) **NEORAL® Oral Solution** (cyclosporine oral solution for microemulsion)

**Cyclosporine**

**Cyclosporine** is indicated for the prevention or treatment of graft-versus-host disease in patients undergoing hematopoietic stem cell transplantation, and for the treatment of various immunologically mediated disorders.

**Adverse Reactions**

The most common adverse reactions reported with cyclosporine are hypertension, hyperlipidemia, hirsutism, diabetes mellitus, and angioedema. Other adverse reactions may include:

- Gastrointestinal: Nausea, vomiting, diarrhea, constipation, dyspepsia, abdominal pain, and motility disorders.
- Dermatological: Rash, pruritus, alopecia, and photosensitivity.
- Hematological: Agranulocytosis, neutropenia, thrombocytopenia, anemia, and lymphopenia.
- Neoplastic: Secondary neoplasms, including lymphomas, squamous cell carcinoma, and basal cell carcinoma, which may require more frequent monitoring and prompt treatment.
- Neurological: Seizures, headaches, and tremors.
- Renal: Renal dysfunction, including azotemia, hyperkalemia, and hyperuricemia.

**Contraindications**

- Hypersensitivity to cyclosporine or any of its components.
- Severe hepatic or renal impairment.
- Active gastrointestinal bleeding.

**Precautions**

- Pregnancy: Use during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus. Avoid use of cyclosporine in pregnant women if possible.
- Breastfeeding: Breastfeeding should be avoided during cyclosporine therapy.

**Drug Interactions**

- Central nervous system depressants, including sedative-hypnotics, antipsychotics, and antidepressants.
- Digitalis glycosides, anticoagulants, and antihypertensives.
- Oral contraceptives, antithyroid agents, and cimetidine.
- Antituberculosis agents, including pyrazinamide and isoniazid.

**Cyclosporine** is extensively metabolized by the cytochrome P-450 3A4 (CYP3A4) system and can interact with many other drugs that are also metabolized by this enzyme system. These interactions can affect cyclosporine levels and the effectiveness of drugs taken concomitantly.

**Summary**

Cyclosporine should be used with caution in pregnant women or in patients of childbearing potential, as it may cause birth defects. Breastfeeding is not recommended during cyclosporine therapy. Close monitoring of renal function is necessary, and cyclosporine levels should be monitored regularly.

**References**


**Novartis Pharmaceutical Corporation**, East Hanover, New Jersey 07936

**REV NOVEMBER 1997 P30771945 9E0539**

**TRANSPORT BRIEF SUMMARY**
VITAL IMMUNOSUPPRESSION FOR VITAL ORGANS.

IN CARDIAC TRANSPLANTS

IN RENAL TRANSPLANTS

Roche Pharmaceuticals
NOW MORE THAN EVER
CellCept®
(mycophenolate mofetil)
250 mg capsules and 500 mg tablets

A STANDARD PART OF THE PROTOCOL

TO PREVENT CARDIAC ALLOGRAFT REJECTION.

In the largest controlled study in cardiac transplantation, CellCept was compared with azathioprine (AZA) in combination with cyclosporine and corticosteroids. No difference was established between CellCept and AZA with respect to biopsy-proven rejection with hemodynamic compromise. CellCept was also shown to be at least as effective as AZA in preventing death or retransplantation at 12 months posttransplant in both the all-patients group (12.8% vs 15.2%, respectively) and the treated-patients group (6.2% vs 11.4%, respectively).

Adverse events reported in >30% of patients receiving either CellCept 3 g/day or AZA 1.5 to 3 mg/kg/day (in combination with cyclosporine and corticosteroids) were pain, fever, headache, asthenia, anemia, leukopenia, hypotension, hypertension, peripheral edema, hypercholesterolemia, hypokalemia, hyperglycemia, creatinine and BUN increased, diarrhea, constipation, nausea, vomiting, respiratory infection, dyspnea, cough increased, lung disorder, insomnia.

The overall incidence of opportunistic infections was approximately 10% higher in patients treated with CellCept than in those receiving AZA, but this difference was not associated with excess mortality due to infection/sepsis among patients treated with CellCept. The CellCept group had more herpes simplex and herpes zoster than the AZA group. (See WARNINGS in brief summary of product information.)

TO PREVENT RENAL ALLOGRAFT REJECTION.

CellCept significantly reduced the incidence of treatment failure over AZA or placebo and substantially reduced the incidence of organ rejection within the first 6 months posttransplantation, when used in combination with cyclosporine and corticosteroids.

The principal adverse events associated with the administration of CellCept include diarrhea, leukopenia, sepsis and vomiting, and there is evidence of a higher frequency of certain types of infections. (See ADVERSE REACTIONS in brief summary of product information.)

CellCept should not be used in pregnant women unless the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should use effective contraception prior to, during and for 6 weeks after CellCept has been stopped. (See WARNINGS and PRECAUTIONS: Pregnancy and Information for Patients in brief summary of product information.)

* Patients should be monitored for neutropenia. If neutropenia develops (ANC <1.3 x 10⁹/L), dosing with CellCept should be interrupted or the dose reduced, appropriate diagnostic tests performed and the patient managed appropriately. See brief summary of product information.

WARNING: Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of renal or cardiac transplant patients should use CellCept. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.
In the AUC of MPA by cholestyramine, caution should be used in the concomitant administration of CellCept with drugs that interfere with the absorption, metabolism, or excretion of MPA. The concurrent use may reduce the efficacy of CellCept (see PRECAUTIONS: Drug Interactions).

For patients with cancer, CellCept therapy should be initiated with the lowest possible effective dose and titrated up according to the patient's response and need. The starting dose of CellCept is 1 g/day in the form of 500 mg tablets (2 x 500 mg tablets) three times a day (TID), and the daily dose should be increased or decreased as necessary to minimize the frequency and severity of adverse events (see CLINICAL PHARMACOLOGY: Pharmacokinetics and DOSAGE AND ADMINISTRATION).

Contraindications: CellCept may be contraindicated in patients with hypersensitivity to mycophenolate mofetil, mycophenolic acid or any component of the drug product.

Precautions: CellCept should be avoided in patients with known or suspected malignancies of the lymphoid system, including lymphoma, or other malignancies, because of the potential for drug-induced malignancies.

CellCept therapy should be considered for patients in whom the potential benefits outweigh the potential risks. The potential benefits should be assessed for each patient individually, and the benefits should be weighed against the risks of the drug for the individual patient.

Adverse Reactions: Adverse reactions associated with the use of CellCept include diarrhea, leukopenia, and decreases in the absolute neutrophil count (ANC). The frequency of these adverse reactions was similar in studies of patients with chronic renal failure and those with acute lymphoblastic leukemia.

For patients receiving CellCept, neutropenia should be monitored (see PRECAUTIONS: Laboratory Tests). The development of neutropenia should be followed by appropriate treatment with supportive measures.

Because of the potential for drug-induced malignancies, all patients receiving CellCept should be monitored for development of any new or unusual tumors or growths.

WANT TO READ MORE? See the full prescribing information for CellCept (mofetil mycophenolate) tablets for the latest information on adverse reactions associated with the use of CellCept.
### Adverse Events in the Controlled Study in Prevention of Renal Allergit Rejection (Controlled)

<table>
<thead>
<tr>
<th>Event</th>
<th>CellCept</th>
<th>Azathioprine</th>
<th>Placebo</th>
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<tr>
<td>Overall incidence</td>
<td>4.2%</td>
<td>12.9%</td>
<td>13.1%</td>
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<tr>
<td>Serious renal events</td>
<td>0.2%</td>
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<td>0.9%</td>
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<td>Major adverse events</td>
<td>0.7%</td>
<td>1.7%</td>
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</tr>
<tr>
<td>Other adverse events</td>
<td>3.7%</td>
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### Adverse Events in the Controlled Study in Prevention of Cardiac Allergit Rejection (Controlled)

<table>
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<tr>
<td>Overall incidence</td>
<td>5.4%</td>
<td>11.3%</td>
<td>12%</td>
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<tr>
<td>Serious renal events</td>
<td>0.8%</td>
<td>1%</td>
<td>1.5%</td>
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<td>2%</td>
<td>2%</td>
</tr>
<tr>
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<td>3.9%</td>
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<td>9.6%</td>
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### Opportunistic Infections in the Prevention of Cardiac Rejection (Controlled)

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### Metabolism and Nutritional

- **Overall incidence**: 12.1%
- **Serious renal events**: 0.8%
- **Major adverse events**: 1.3%
- **Other adverse events**: 3.9%

### Opportunistic Infections in the Prevention of Renal Allergit Rejection (Controlled)

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Dialysis keeps her going.
Today, a growing consensus supports managing ESRD patients in the upper half of the 30–36% hematocrit range.

- New NKF-DOQI guidelines recommend hematocrits of 33–36%.¹

- Two new studies suggest an association between hematocrits of 33–36% and reduced hospitalization.²³ Reduced hospitalization may reduce the cost of care.

The future? Hematocrits higher in the target range mean more dialysis patients can be feeling better. Doing better. And going stronger.

Let's keep it up.

Recommended Hematocrit Ranges

**EPOGEN**

(RECOMBINANT)

**HIGHER HEMATOCRITS LEAD TO BETTER OUTCOMES.**

*The EPOGEN® package insert recommends a target hematocrit range of 30% to 36%.*

EPOGEN® is indicated for the treatment of anemia in dialysis patients with chronic renal failure. Patients who receive EPOGEN® may experience adverse effects such as hypertension or flu-like symptoms.

Please see brief summary of prescribing information on following pages.

INDICATIONS AND USAGE — EPOGEN® is indicated for the treatment of anemia associated with chronic renal failure (CRF), including patients on dialysis (end-stage renal disease) and patients not on dialysis, to increase the red blood cell count in patients whose anemia is caused by the hematocrit (HCT) or hemoglobin determinations and to decrease the need for transfusions in these patients.

CONTRAINDICATIONS — EPOGEN® is contraindicated in patients with: 1) uncontrolled hypertension; 2) drug allergy to EPOGEN® or any excipient in its formulation; or 3) known hypersensitivity to human alpha globulins. It is also contraindicated in patients with active neoplastic disorders or infections.

WARNINGS — Pediatric Use: The multilobe preserved formulation contains benzyl alcohol. Benzyl alcohol has been associated with a syndrome of nasal, ear, and skin lesions characterized by cracking, erosion, and desquamation in newborns and infants. In addition, benzyl alcohol has been associated with serious adverse events, including fatalities, in preterm newborns. It is recommended that benzyl alcohol be avoided in the aesthetic formulation of injectable products administered to infants. (See WARNINGS.)
INTRODUCING ATACAND®
A NEW SIGN OF POWER
IN BP REDUCTION

Once-A-Day
NEW
n
atacand
CANDESARTAN CILEXETIL
A new angiotensin II receptor blocker (ARB) with power @ every dose

- New once-daily ATACAND has significant power to reduce blood pressure (BP) at the 16-mg starting dose. And a dosage increase to 32 mg leads to an even greater reduction in BP.¹

- ATACAND delivers effective BP reduction when compared to amlodipine at the starting doses and to enalapril (at doses of 10 mg enalapril, 8 mg ATACAND).²³

USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, ATACAND should be discontinued as soon as possible. See WARNINGS, Fetal/Neonatal Morbidity and Mortality.

Volume- and/or salt-depletion should be corrected prior to administering ATACAND or symptomatic hypotension may occur.

The most common adverse events that occurred with ATACAND in placebo-controlled clinical trials were URI (6%), dizziness (4%), and back pain (3%).

Before prescribing ATACAND, please see accompanying brief summary of Prescribing Information on adjacent page.
Exhibits a long-lasting effect on the AT$_1$ receptor site for 24-hour control.

- ATACAND gets at the site where angiotensin II causes vasoconstriction.
- ATACAND stays at the site, where its antihypertensive effect is not overcome by angiotensin II.

Prescribe new ATACAND tablets—and Get the Power!
ATACAND: GET THE POWER™

• Powerful BP reduction @ the starting dose.
• First line for hypertensive patients.
• Convenient once-daily dosing for 24-hour BP reduction.
• Usual starting dose: 16 mg once daily.

BRIEF SUMMARY

Before prescribing, please see full Prescribing Information for ATACAND.

USE IN PREGNANCY

When used in pregnant women, drugs that act directly on the renin-angiotensin system can cause fetal injury and even death in the developing fetus. When pregnancy is detected, ATACAND should be discontinued as soon as possible. See WARNINGS, Fetal/Neonatal Morbidity and Mortality.

ATACAND® (candesartan cilexetil) was effective in reducing blood pressure regardless of race, although the effect was somewhat less in blacks (usually a low-renin population).

CONTRAINdicATIONS: ATACAND is contraindicated in patients who are hypersensitive to any component of this product.

WARNINGS: Fetal/Neonatal Morbidity and Mortality: Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Several cases have been reported in the world literature in patients who were taking angiotensin converting enzyme inhibitors. When pregnancy is detected, ATACAND should be discontinued as soon as possible. The use of drugs that act directly on the renin-angiotensin system during the second and third trimesters of pregnancy has been associated with fetal and neonatal morbidity and mortality, including intra-uterine growth retardation, oligohydramnios, umbilical cord abnormalities, and cleft lip and/or palate. Newborns (0-1 months) may be at increased risk of neonatal morbidity and mortality if exposed to ATACAND in utero. Therefore, ATACAND should be discontinued prior to or at the time of delivery. These effects can manifest as reduced birth weight, skeletal abnormalities, hypoglycemia or oligohydramnios, which may result in neonatal death. In utero exposure to ATACAND was also associated with increased rates of premature closure of the ductus arteriosus. Superficial thrombophlebitis and/or phlebitis, and thrombosis have been reported in newborns exposed to ATACAND in utero. Patients born to women treated with ATACAND should be monitored for the occurrence of hypoglycemia, especially if they are infants of diabetic mothers. Hypoglycemia is also reported in nursing infants of mothers treated with ATACAND. Infants born preterm or with low birthweight exposed to ATACAND in utero may be at increased risk of symptomatic hypoglycemia. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother. ATACAND has also been shown to cause fetal and neonatal deaths, including fetal hydrops, in several animal species and in women. Fetal/Neonatal Morbidity and Mortality: Adverse events observed in clinical trials of ATACAND (candesartan cilexetil), 31% had 65 and over, while 3% were 75 and over. No overall differences in safety or effectiveness were observed between these subgroups of younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Extreme caution has been used in controlled trials of about 200 elderly hypertensive patients (ages 65 to 78 years), administration of candesartan cilexetil was well tolerated and lowered blood pressure by about 136 mmHg more than placebo.

ADVERSE REACTIONS: ATACAND has been evaluated for safety in more than 3600 patients/subjects, including more than 2020 patients treated for hypertension. About 900 of these patients were studied for at least 6 months and about 200 for more than 1 year. In general, treatment with ATACAND was well tolerated. The overall incidence of adverse events reported with ATACAND was similar to placebo. The rate of withdrawals due to adverse events in all trials in patients (7510 total) was 3.3% (e.g., 109 of 3020) of patients treated with candesartan cilexetil in monotherapy and 3.5% (e.g., 280 of 8000) treated with placebo. In placebo-controlled trials, discontinuation of therapy due to clinical adverse events occurred in 2.4% (e.g., 57 of 2350) of patients treated with ATACAND and 3.4% of patients treated with placebo. The most common reasons for discontinuation of therapy with ATACAND (candesartan cilexetil) (3.2%). The adverse experiences occurred in placebo-controlled clinical trials at a more than 1 rate but at the same or greater incidence in patients treated with placebo. The most common adverse events were: headache (6% vs. 3%), dizziness (4% vs. 3%), upper respiratory tract infection (8% vs. 4%), pharyngitis (2% vs. 1%), and skin rash (2%). The following adverse events are listed by system organ class: the most common adverse events are listed by preferred term:


NEW ATACAND Candesartan Cilexetil

Please see adjacent brief summary of Prescribing Information.

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Application for Associate Membership

Associate Members must be fellows or postgraduate trainees in nephrology or a related discipline, and reside in North or Central America.

LAST NAME
FIRST NAME
MIDDLE INITIAL(S)

Preferred Mailing Address

City
State/Province
ZIP/Postal Code
Country

Business Address (If not listed above)

City
State/Province
ZIP/Postal Code
Country

Business Telephone
Business Fax
E-Mail Address

Date of Birth
Sex
Country of Citizenship

If you reside in the United States, but are not a U.S. citizen, please provide visa status:

Dates of Fellowship (Month and year)
Beginning
Ending

Location of Fellowship (List all department affiliations)


Primary Professional Interest (e.g., adult nephrology, pediatric nephrology, pathology, urology, physiology, etc.)

Primary Institutional Affiliation (e.g., medical school-faculty/clinical dept., medical school-faculty/research dept., hospital-staff/clinical staff, private practice, armed forces or other federal services, etc.)

Please indicate the amount of time spent on the following activities. Your total should amount to 100 percent.

Clinical
Research
Teaching
Administration
Other

List other societies to which you belong.

For office use only:

ID#: Date entered: Check#: Check name:
Professional Education and Training

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Publications *(if any)*

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Provide names and addresses of three persons from whom letters of reference may be requested if needed.

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I certify that the applicant is in training and therefore entitled to Associate Membership.

Director’s Name *(print)*          Director’s Signature

Please return your completed application with the first year’s dues *(see below)* payable to the ASN in U.S. funds.

$35 - ASSOCIATE MEMBERSHIP

☐ Check *(Payable in U.S. dollars)*

If you would like to pay by VISA or MasterCard, please list the cardholder’s name, number and expiration date below:

☐ VISA       ☐ MasterCard

Cardholder’s Name *(please print or type)*    Signature

Card Number    Expiration Date

Mail completed form and $35 payment to:    American Society of Nephrology
                                           1200 19th Street, NW, Suite 300
                                           Washington, DC 20036-2422
Introducing the Transplant Learning Center

...Because a Little Extra "TLC" Can Make a Big Difference

- An innovative, interactive lifestyle management program for transplant recipients and their health care teams*

- Addresses issues critical to long-term graft success and the long-term health and emotional well-being of transplant recipients

- Developed and overseen by an Advisory Board of experts in transplantation and related fields

- Brought to you by the world leader in transplant medicine, Novartis, the maker of Neoral® (cyclosporine for microemulsion) and Sandimmune® (cyclosporine, USP)

For more information about the TLC Program, talk to your Novartis representative or call toll free 1-888-TLCENTER (852-3683).

Transplant Learning Center
Learning for a Lifetime

*Provided free to eligible solid-organ recipients, 18 years and older, who take Neoral® or Sandimmune®. Please see brief summary of prescribing information and boxed warning for Neoral on the adjacent page.

Novartis
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936
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Printed in U.S.A.
NEORAL Soft Gelatin Capsules (cyclosporine capsules for microemulsion)

**SUMMARY**

Neoral® Oral Solution (cyclosporine oral solution for microemulsion) should be administered with a sucrose-based solution, preferably with orange or cranberry juice, to reduce the risk of taste. The formulation of Neoral® Oral Solution (cyclosporine oral solution for microemulsion) with milk can be unpalatable.

Patients should be advised to take Neoral® on a consistent schedule with regard to time of day and relation to meals. Grapefruit juice and alcohol can affect cyclosporine blood concentrations. These patients should be monitored.

Neoral® Oral Solution (cyclosporine oral solution for microemulsion) is contraindicated in patients with histories of alcohol abuse, drug abuse or a known high incidence of adverse drug reactions. Patients with a history of alcohol abuse and/or drug abuse should be screened for alcohol or drug abuse and monitored closely.

**ADVERSE REACTIONS**

Cyclosporine-induced nephrotoxicity may be reduced by use of Neoral® Capsules as compared to Sandimmune® tablets. Neoral® is available in capsules, but Sandimmune® is available in tablets. Neoral® is recommended for use in patients with severe renal impairment or who have already received standard dosages of Sandimmune®.

**WARNINGS AND PRECAUTIONS**

Adverse effects are more common in patients receiving Neoral® and Sandimmune® tablets. Neoral® is recommended for use only in patients who have previously received Sandimmune® tablets. The potential benefits of Neoral® should be weighed against the potential risks in individual patients. Neoral® is superior to Sandimmune® in patients with severe renal impairment or who have already received standard dosages of Sandimmune® tablets.

**CLINICAL PHARMACOLOGY**

Cyclosporine has a unique mechanism of action as an immunosuppressant, with a relatively low risk of toxicity compared with other immunosuppressants. Neoral® Capsules are an improved formulation of cyclosporine microemulsion, which may be less nephrotoxic than Sandimmune® tablets.

**DOSAGE AND ADMINISTRATION**

Neoral® Capsules are recommended for use only in patients who have previously received Sandimmune® tablets. Neoral® is superior to Sandimmune® in patients with severe renal impairment or who have already received standard dosages of Sandimmune® tablets.

**REPLACEMENT THERAPIES**

Neoral® Capsules are not intended to be used as a replacement therapy for cyclosporine microemulsion.
When it comes to getting recommendations on patient care and treatment, most physicians consult a colleague.

Now you can consult with dozens of leading experts in your specialty with UpToDate — a revolutionary CD-ROM program that is available to you 24 hours a day, every day. UpToDate answers your clinical questions and provides current information on important new trials, studies and treatment protocols. The result is that you will make confident decisions more quickly and have more time for your patients.

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Each UpToDate CD-ROM disk includes the equivalent of 25,000 pages of essential, up-to-date information, arranged in an easy-to-access, convenient way. You receive a new disk every four months, which completely replaces the old one.

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Phone: (781) 237-4788
Fax: (781) 239-0391
E-mail: sales.uptodate@bdrinc.com

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<td>SUNY Health Science Center at Brooklyn</td>
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<td>Burton D. Rose</td>
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<td>William M. Bennett</td>
<td>University of Oregon Health Sciences Center</td>
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Take 5 minutes and download a demo at: www.uptodateinc.com
Dexferrum
(Iron Dextran Injection, USP)

For effective intravenous treatment of iron deficiency anemia, it positively delivers.

Decreases total iron binding capacity.
Increases transferrin saturation.
For your patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible, depend on DEXFERRUM for quality intravenous treatment. Here's why:

- A recent study demonstrated that rapid iron utilization to replete iron stores and produce new hemoglobin takes place soon after DEXFERRUM administration.¹
- The study noted that DEXFERRUM significantly decreases total iron binding capacity and increases transferrin saturation.

<table>
<thead>
<tr>
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<th>Day 30</th>
<th>Effect of Iron Dextran (probability value)</th>
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<tr>
<td>Serum TIBC (µg/dl)</td>
<td>221.2±40.9</td>
<td>201.3±51.6</td>
<td>183.2±48.6</td>
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<tr>
<td>Transferrin saturation (%)</td>
<td>14.3±2.8</td>
<td>32.3±13.0</td>
<td>22.9±3.3</td>
<td>&lt;0.0001</td>
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Study was conducted to determine the rate and extent of iron utilization after administration of intravenous iron dextran and to compare the efficacy of iron dextran of different molecular weights. Twenty patients were randomized to receive either a 500 mg dose of DEXFERRUM (267,000 daltons) or INFeD® (96,000 daltons) administered in five sequential 100 mg doses. Indices of iron status were examined before treatment and at weekly intervals up to four weeks later.

- The safety and efficacy of DEXFERRUM have been confirmed through clinical trials in end-stage renal disease (ESRD) patients on epoetin alfa.²

For more information, or to order DEXFERRUM, call us toll-free at 1-800-645-1706.

Call our Reimbursement Hotline at 1-800-282-7712 regarding DEXFERRUM reimbursement issues or our Patient Assistance Program. In the Washington, D.C., metropolitan area call 1-202-942-2453.

Warning

The parenteral use of complexes of iron and carbohydrates has resulted in anaphylactic-type reactions. Deaths associated with such administration have been reported. Therefore, DEXFERRUM should be used only in those patients in whom the indications have been clearly established and laboratory investigations confirm an iron-deficient state not amenable to oral iron therapy.

2. Data on file at American Regent Laboratories, Inc.

Please see brief summary of the prescribing information on the following page.
DEXFERRUM®
(IRON DEXTRAN INJECTION, USP)

WARNING
THE PARENTERAL USE OF COMPLEXES OF IRON AND CARBOHYDRATES HAS RESULTED IN ANAPHYLACTIC-TYPE REACTIONS. DEATHS ASSOCIATED WITH SUCH ADMINISTRATION HAVE BEEN REPORTED. THEREFORE, DEXFERRUM SHOULD BE USED ONLY IN THOSE PATIENTS IN WHOM THE INDICATIONS HAVE BEEN CLEARLY ESTABLISHED AND LABORATORY INVESTIGATIONS CONFIRM AN IRON DEFICIENT STATE NOT AMENABLE TO ORAL IRON THERAPY.

DESCRIPTION: DEXFERRUM® (IRON DEXTRAN INJECTION, USP) is a dark brown, viscous sterile liquid complex of ferric oxyhydroxide and a low molecular weight dextran derivative for intravenous use. Each mL contains 30 mg elemental iron as an iron dextran complex. Sodium chloride may have been added for isotonicity. Water for injection is pH adjusted to 3.2 - 4.6 with hydrochloric and/or, if necessary, sodium hydroxide. Sterile, nonpyrogenic.

Therapeutic Class: Hematologic
INDICATIONS AND USAGE: DEXFERRUM is indicated for treatment of patients documented iron deficiency in whom oral administration is unfeasible or impossible.

CONTRAINDICATIONS: Hypersensitivity to the product. All anemias associated with iron deficiency.

WARNING: SEEN BOXED WARNING.

A risk of anaphylaxis may attend the intravenous injection of iron-carbohydrate complexes. Such complexes have been found under experimental conditions to produce sarcoid when large doses or small doses injected repeatedly at the same site were given to rats, mice, and rabbits, and possibly in humans.
The long latent period between the injection of a potential carcinogen and the appearance of a tumor makes it impossible to measure accurately the risk in man. These have, however, been several reports in the literature describing tumors at the reaction site in humans who had previously received intravenous injections of iron-carbohydrate complexes. Large intravenous doses, such as used with total dose infusions (TDI), have been associated with an increased incidence of hemochromatosis. The adverse effects typically delayed 7 to 9 days reactions typified by one or more of the following symptoms; arthralgia, backache, chills, diarrhea, moderate to high fever, headache, malaise, myalgia, weakness, nausea, and vomiting. The onset is usually 3-4 days after administration and symptoms generally subsides within 3-4 days. The etiology of these reactions is not known. The potential for a delayed reaction must be considered when estimating the lack of benefit of treatment.
The maximum daily dose should not exceed 2 mL undiluted iron dextran.

This preparation should be used with extreme care in patients with serious impairment of liver function.

It should not be used during the acute phase of infectious liver disease.

Adverse reactions experienced following administration of DEXFERRUM may exacerbate cardiovascular complications in patients with pre-existing cardiovascular disease.

PRECAUTIONS: General: Unusual reactions to parenteral iron will cause access of iron to the liver and in some cases to the heart.

Anaphylaxis and other hypersensitivity reactions have been reported after uneventful test doses as well as therapeutic doses of iron dextran injection. Therefore, administration of subsequent test doses during therapy should be considered. Patients should be observed for anaphylactic reactions for at least 2 hours after administration.

Epinephrine is immediately available in the event of acute hypersensitivity reactions. (Usual adult dose: 0.5 mL of 1:1000 solution, subcutaneous or intravenous injection.) Note: Patients using beta-blocking agents may not respond adequately to epinephrine. Unattended or similar beta agonists may be required in these patients.

Patients who are known or suspected to have a history of intolerance of dextran products should not be administered DEXFERRUM.

Informed Consent Patients: Patients should be advised of the potential adverse reactions associated with the use of DEXFERRUM.

Drug/Laboratory Test Interactions: Large doses of iron dextran (3 mL or more) have been reported to give a brown color to serum from a blood sample drawn hours after administration.

The patient may cause falsely elevated values of serum bilirubin and falsely decreased values of serum calcium.

Serum iron determinations subsequent to colistimethate assay may not be meaningful for 3 weeks following the administration of iron dextran.

Serum lactate dehydrogenase levels may be elevated 4 to 9 days after an intravenous dose of DEXFERRUM and slowly to return to baseline after about 3 weeks.

Examination of the bone marrow for iron scores may not be meaningful for prolonged periods following iron dextran therapy because residual iron dextran may remain in the reticuloendothelial cells.

Some scores with this labelled bone seeking agent, in the presence of high serum ferritin levels or following iron dextran infusions, have been reported to show reduction of bone uptake, marked renal activity, and excessive blood pool and soft tissue accumulation.

Cardiomegaly, Metabolism, Impairment Of Fertility: See WARNINGS

Pregnancy: Teratogenic Effects: Pregnancy Category C. Iron dextran has been shown to be teratogenic and embryotoxic in mice, rats, rabbits, dogs and monkeys when given in doses of about 3 times the maximum human dose. No consistent adverse effect patterns were observed. Experiments are needed in dogs and monkeys to assess whether the teratogenic and embryotoxic activity is dose-related.

It is unknown whether iron dextran is excreted in human milk. For this reason, iron dextran injection is not recommended for nursing women.

The risk/benefit ratio should be considered for each individual patient.

Intravenous infusions of iron dextran have been used in the treatment of pregnant women with iron deficiency anemia (suspected or confirmed) in whom oral iron therapy is not practical. The incidence of side effects is similar to that observed in non-pregnant patients receiving iron dextran. This method of treatment is not considered to be recommended for routine use in pregnant women. The possibility of anaphylactic reactions to iron dextran in pregnancy cannot be overlooked. The risk/benefit ratio should be considered for each individual patient.

Placental Transfer: Various animal studies and studies in pregnant humans have demonstrated incoercible results with respect to the placentar transfer of iron dextran as iron dextran. It appears that some iron does reach the fetus, but the form in which it crosses the placenta is not clear.

Maternal Bleeding: Caution should be exercised when DEXFERRUM is administered to a nursing woman. Transfused iron dextran is excreted in human milk.

Pediatric Use: Use in infants and children 0-11 months of age is based on experience with DEXFERRUM given orally, intramuscularly and intravenous administrations in various cases. Use of parenteral administrations in infants and children is not recommended. No data are available on the use of DEXFERRUM during infancy.

Adverse Reactions: Dermatologic: Erythema, pruritus, purpura, rash
Gastrointestinal: Abdominal pain, nausea, vomiting, diarrhea.
Hematologic/Myelogenous: Leucocytosis, leucopenia, thrombocytopenia.
Neurologic/Neuromuscular: Arthralgia, arthritis (mild transient reaction in patients with quiescent rheumatoid arthritis). See PRECAUTIONS, General. Myalgia, backache, sterile abscess, bone pain and/or underlying tissue desiccation (swelling), cellulitis, swelling, inflammation, local phlebitis or at or near intravenous injection site.
Neuropsychiatric: Convulsions, seizures, syncope, headache, weakness, unresponsiveness, paraesthesia, fabre episodes, chills, dizziness, delirium, numbness.
Respiratory: Respiratory arrest, dyspnea, bronchospasm.
Urogenital: Hematuria.
Delayed reactions: Arthralgia, backache, chills, diarrhea, fever, headache, malaise, myalgia, nausea, vomiting. (See WARNINGS)
Miscellaneous: Fabre episodes, swelling, shrinking, chills, malaise, altered taste.

DOSEAGE AND ADMINISTRATION: Oral iron should be discontinued prior to administration of DEXFERRUM.

Intravenous Infusion: PRIOR TO RECEIVING THEIR FIRST DEXFERRUM THERAPEUTIC DOSE, ALL PATIENTS SHOULD BE GIVEN AN INTRAVENOUS TEST DOSE OF 0.5 mL. (See PRECAUTIONS, General). THE TEST DOSE IS ADMINISTERED AS A SLOW (1 MIN) INFUSION. If the patient has no symptoms, the test dose is then repeated, if necessary, and the therapeutic dose is given.

DEXFERRUM should be administered as a slow IV infusion of 0.5 mL over 15 minutes, unless otherwise indicated. In the event of an anaphylactic reaction, the patient should be given the usual emergency treatment at appropriate concentrations to prevent or treat anaphylaxis. The patient should be instructed to remain at the hospital for 6-12 hours after the administration of DEXFERRUM.

For Transfer Patients: Patients should be advised of the potential adverse reactions associated with the use of DEXFERRUM.

Drug/Laboratory Test Interactions: Large doses of iron dextran (3 mL or more) have been reported to give a brown color to serum from a blood sample drawn 4 hours after administration.

The patient may cause falsely elevated values of serum bilirubin and falsely decreased values of serum calcium.

Serum iron determinations subsequent to colistimethate assay may not be meaningful for 3 weeks following the administration of iron dextran.

Serum lactate dehydrogenase levels may be elevated 4 to 9 days after an intravenous dose of DEXFERRUM and slowly to return to baseline after about 3 weeks.

Examination of the bone marrow for iron scores may not be meaningful for prolonged periods following iron dextran therapy because residual iron dextran may remain in the reticuloendothelial cells.

Some scores with this labelled bone seeking agent, in the presence of high serum ferritin levels or following iron dextran infusions, have been reported to show reduction of bone uptake, marked renal activity, and excessive blood pool and soft tissue accumulation.

This is a brief summary; see product package insert for full prescribing information.

AMERICAN REGENCY LABORATORIES, INC.
SHIRLEY, NY 11967

Rev. 3/97
For your ESRD patients...
Abbott introduces
Zemplar™
(Paricalcitol Injection).

Advancing the management of secondary hyperparathyroidism.
Zemplar™ (Paricalcitol Injection) with minimal effect on calcium

Zemplar rapidly reduces PTH.
- In placebo-controlled clinical studies with ESRD patients, Zemplar achieved a mean PTH reduction of 30% within 6 weeks.²
- Zemplar reduced PTH 60% in only 12 weeks.³
- There was no difference in incidence of hypercalcemia or hyperphosphatemia when compared to placebo.⁴,³

Phase III results in ESRD patients.³

Pooled results from Zemplar-treated patients in 3 double-blind, placebo-controlled, dose-escalating 12-week studies. Doses initiated at 0.04 mcg/kg and titrated by 0.04 mcg/kg every 2 weeks, depending on response.³

Zemplar from Abbott.
- Allows aggressive treatment of mild to severe secondary hyperparathyroidism.
- May be administered at any time during dialysis.⁴
- Available in convenient vials.

Important safety considerations.
Zemplar is contraindicated in patients with vitamin D toxicity, hypercalcemia, or hypersensitivity to product ingredients. Phosphate or vitamin D-related compounds should be discontinued.

Administration may place patients at risk for hypercalcemia, elevated Ca x P product, and metastatic calcification.

Therefore, monitoring of serum calcium and phosphorus levels is necessary.
If hypercalcemia develops, the dose should be reduced or interrupted.

For more information, call your Abbott Renal Care representative or 1-800-457-9472. Also visit us at www.abbottrenalcare.com

* NOTE: Serum phosphorus, calcium and calcium x phosphorus product (Ca x P) may increase when Zemplar is administered.
suppresses PTH and phosphorus.\textsuperscript{*,1}
ZEMPLAR® (paricalcitol injection) is a synthetic vitamin D analog. It is available as a sterile, clear, colorless aqueous solution for intravenous administration containing paricalcitol, 5 mcg, procyclidine hydrochloride, 30% (w/v), and alcohol, 20% (v/v).

Paricalcitol is a white powder chemically designated as 19-nor-1,25-(OH)2 vitamin D3 (9α, 11β, 19-nor-1,25-(OH)2-calcitriol). It has the following structural formula:

Molecular formula is C27H44O3.
Molecular weight is 418.65.

CLINICAL PHARMACOLOGY
Mechanism of Action
Paricalcitol is a synthetic vitamin D analog. Vitamin D and paricalcitol have been shown to reduce parathyroid hormone (PTH) levels.

Pharmacokinetics
The pharmacokinetics of paricalcitol have been studied in patients with chronic renal failure (CRF) requiring hemodialysis. Zemplar® is administered as an intravenous bolus injection. Within two hours after administering doses ranging from 0.5 to 2.4 mcg/kg, concentrations of paricalcitol decreased rapidly, with 50% of the concentration of paricalcitol declined by a mean half-life of about 15 hours. No accumulation of paricalcitol was observed with multiple dosing.

Elimination
In healthy subjects, plasma radioactivity after a single 0.16 mcg intravenous bolus dose to a patient was distributed to the parent drug. Paricalcitol was eliminated primarily by hepatobiliary secretion, as 74% of the radioactive dose was recovered in feces and only 10% was found in urine.

Metabolism
Several unknown metabolites were detected in both the urine and feces, with no detectable paricalcitol in the urine. These metabolites have not been characterized and have not been identified. Together, these metabolites contributed 51% of the urinary radioactivity and 35% of the fecal radioactivity. In vitro plasma protein binding of paricalcitol was extensively (>95%) and nonsaturable over the concentration range of 1 to 100 ng/ml.

Paricalcitol Pharmacokinetic Characteristics in CRF Patients 0.6 mcg/kg dose
Parameter Value (Mean ± SD)
Cmax (5 min. after bolus) 6
1850 ± 664 (µg/mL)
AUC 5
2738 ± 820 (µg·h/L)
CL 5
0.72 ± 0.24 (L/hr)
Vd 5
6 ± 2 (L)

Laboratory Tests
In placebo-controlled studies, paricalcitol reduced serum total alkaline phosphatase levels.

Special Populations
Paricalcitol pharmacokinetics have not been investigated in special populations (geriatric, pediatric, hepatic insufficiency), or for drug–drug interactions. Pharmacokinetics were not gender-dependent.

Clinical Studies
In three 12-week, placebo-controlled, phase 3 studies in chronic renal failure patients on dialysis, the dose of Zemplar® was started at 0.5 mcg/kg 2 times per week and titrated up to a maximum of 2 mg/kg every 2–3 weeks. Paricalcitol’s effects on parathyroid hormone (PTH) levels were reduced at least 20% from baseline and a further escalation brought the dose to 0.6 mcg/kg. PTH fell to less than 100 pg/mL. In the 200 µg/kg product was greater than 75% within any 3-week period, or serum calcium became greater than 11.5 mg/dL at any time. Patients treated with paricalcitol showed a mean PTH reduction of 20% within 5 weeks. In these studies, there was no significant difference in the incidence of hypocalcemia, hypercalcemia, or hyperparathyroidism levels in patients treated with Zemplar® and placebo-treated patients. The results from these studies are as follows:

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Change</th>
<th>Baseline Mean</th>
<th>Change from Baseline</th>
<th>Final Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zemplar®</td>
<td>-0.39</td>
<td>670</td>
<td>281 (307–719)</td>
<td>-379 (±127)</td>
</tr>
<tr>
<td>Placebo</td>
<td>740</td>
<td>330 (287–1671)</td>
<td>±86 (±144.3)</td>
<td></td>
</tr>
<tr>
<td>Alkaline Phosphatase (U/L)</td>
<td>120 (40–500)</td>
<td>±41.5 (±1596.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phosphorus (µmol/L)</td>
<td>98 (90–150)</td>
<td>±2.0 (±31.0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium (mg/dL)</td>
<td>9.3</td>
<td>±0.7 (±12.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(mg/dL)</td>
<td>±0.2 (±0.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phosphorus (mg/dL)</td>
<td>5.8</td>
<td>±3.7 (±10.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium × Phosphorus Product (mg²/dL)</td>
<td>54</td>
<td>±32 (±100)</td>
<td>±7.9 (±2.0)</td>
<td></td>
</tr>
</tbody>
</table>

INDICATIONS AND USAGE
Zemplar® is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure. Studies in patients with chronic renal failure show that Zemplar® suppresses PTH levels with no significant risk of hypercalcemia or hyperphosphatemia when compared to placebo. Moreover, the serum phosphorus, calcium and calcium × phosphorus product (Ca × P) may increase when Zemplar® is administered.

CONTRAINDICATIONS
Zemplar® should not be given to patients with evidence of vitamin D toxicity, hypercalcemia, or hyperphosphatemia (e.g., secondary hyperparathyroidism) unresponsiveness to any ingredient in this product (see PRECAUTIONS; General).

WARNINGS
Acute overdose of Zemplar® may cause hypercalcemia, and require emergency attention. During dose adjustment, serum calcium and phosphorus levels should be monitored closely (e.g., twice weekly). If clinically significant hypercalcemia develops, dose should be reduced or interrupted. Chronic administration of Zemplar® may place patients at risk of hypercalcemia. 

Carcinogenicity studies in rats and mice have not been done with Zemplar®.

Adverse Reactions
In clinical trials of Zemplar® in CRF patients, 4% of patients reported gastrointestinal symptoms, including nausea, vomiting, diarrhea, and constipation.

ANNOUNCEMENTS

26th Annual Seminar in Pediatric Nephrology: Millennium Mandate
The 26th Annual Seminar in Pediatric Nephrology: Millennium Mandate will be held February 26 through March 2, 1999, at the Fontainbleau Hilton Resort and Spa in Miami Beach, Florida. The meeting is sponsored by the Department of Pediatrics, University of Miami School of Medicine. For more information, contact Dr. Jose Strauss, Division of Pediatric Nephrology, University of Miami School of Medicine, P.O. Box 016960, Miami, FL 33101. Telephone: (305) 585-6726; fax: (305) 547-1709; e-mail: jstrauss@peds.med.miami.edu. Or visit the website at http://pediatrics.med.miami.edu/nephrology.htm.

2nd Finlayson Colloquium on Urolithiasis: Calcium Oxalate Nephrolithiasis
The second Finlayson Colloquium on Urolithiasis will be held January 29 to 31, 1999, at the University of Florida, Gainesville, FL. The program will consist of symposia followed by roundtable discussions and will include the following topics: Sites and Mechanisms of Crystal and Stone Formations; Crystal/Tissue Interactions; Modulators of Crystallization; Oxalate and Its Transport; Lithotripsy and Other Therapies. Presentations are by invitation only. For more information, contact Dr. Saeed R. Khan, Department of Pathology, Box 100275, College of Medicine, University of Florida, Gainesville, FL 32610-0275. Telephone: (352) 392-3473; fax: (352) 846-0155; e-mail: mirza.pathology@mail.health.ufl.edu.

Urolithiasis 2000: The IXth International Symposium on Urolithiasis February 13-17, Cape Town, South Africa
The program will include sessions on lithotripsy, endourology, metabolic evaluation, medical therapies, epidemiology, economics of stone disease, role of diet and other nutritional factors, biochemical risk factors, physical chemistry, crystallization modulators, crystal-cell interaction, transport physiology, and urolithiasis in animals. Pre- and post-conference tours including game reserve safari are planned. For more information, contact Professor Allen Rodgers, Symposium Chairman, Chemistry Department, University of Cape Town, South Africa 7701 (Telephone: 27 21 6502572, Fax: 27 21 6867647, e-mail: allenr@psipsy.uct.ac.za).

Advanced Nephrology: Nephrology for the Consultant
A Continuing Medical Education conference, “Advanced Nephrology: Nephrology for the Consultant,” will be held February 4–6, 1999, at the Coronado Island Marriott Resort, Coronado, California. The program is sponsored by the Division of Nephrology, Department of Medicine, University of California, San Diego. The registration fee is $425 for physicians in practice and $175 for residents and fellows. The program offers 17 hours of AMA Category 1 accreditation. For more information, contact Shirley Kolkey at 1660 Hotel Circle North, #220, San Diego, CA 92108. Telephone: (619) 299-6673; fax: (619) 299-6675; e-mail: c-c-m@worldnet.att.net.

4th International Conference on Continuous Renal Replacement Therapies (CRRT)
The Fourth International Conference on Continuous Renal Replacement Therapies will be held March 11 to 13, 1999, at the Hotel del Coronado in San Diego, California. This conference is a unique international symposium featuring a forum for multidisciplinary interactions between physicians, nurses, support personnel, and industry involved in the care of the critically ill patient. The program will include invited lectures, panel discussions, interactive workshops, and oral and poster presentations. Major topics to be addressed include: evolving concepts in the pathophysiology and management of the critically ill patient; practice of CRRT and standardization of care; renal replacement and renal support; experience and controversies with CRRT. For more information, contact Shirley Kolkey Complete Conference Management, 1660 Hotel Circle North, #220, San Diego, CA 92108. Telephone: (619) 299-6673; fax: (619) 299-6675; e-mail: c-c-m@worldnet.att.net.

Official Satellite Symposium to the XVth ICN Iguazu Falls, May 7–9, 1999
After the XVth International Congress of Nephrology in Buenos Aires, Argentina, a satellite meeting on “Advances in the Pathogenesis and Treatment of Renal Osteodystrophy” will be held at Iguazu Falls (the spectacular waterfalls are located between Argentina and Brazil) May 7–9, 1999. The participants will fly from Buenos Aires to Iguazu Falls (Argentinean side) on May 7 and travel by bus to the Brazilian side where the meeting will be held (May 7, registration and evening reception). The organizing committee members are Drs. Eduardo Slatopolsky from the United States and Jorge Cannata from Spain. American citizens will require a visa to enter Brazil. Participants from other countries should check with their Brazilian consulate. For more information, contact BAYFEM Organization by fax at (54-1) 812-1021 or by e-mail at bayfem@ibm.net.

5th International Conference on Geriatric Nephrology and Urology
The 5th International Conference on Geriatric Nephrology and Urology will be held in Salamanca, Spain, October 21 to 23, 1999. Main topics will include: glomerular diseases and vasculitis, osteopathies in the elderly, diabetic nephropathy and hypertension in the elderly, urinary incontinence, renal handling of electrolytes in the elderly, hemodialysis and the elderly, CAPD, acute renal failure in the elderly, and benign prostate hyperplasia. Free communications on geriatric nephrology and urology will be also admitted. For more information, contact Prof. José M. López-Novoa, 5th International Conference on Geriatric Nephrology and Urology, Department of Physiology and Pharmacology, University of Salamanca, Campus Unamuno, 37007 Salamanca, Spain. Telephone: 34 923 294472; fax: 34 923 294669; e-mail: jmhnovoa@gugu.usal.es.
Errata

Due to a typographical error on the original manuscript, the name of the first author was misspelled in the article, "11β-Hydroxysteroid Dehydrogenase, Mineralocorticoid Receptor, and Thiazide-Sensitive Na-Cl Contransporter Expression by Distal Tubules" (J Am Soc Nephrol 9: 1347–1358, 1998). The correct spelling is Magdalena Bostanjoglo.

Due to a copy editing error, the page range in the legend for the cover picture after the Table of Contents in the October 1998 issue was incorrect. The pages are 1861–1872.

XVth International Congress of Nephrology and XIth Latin American Congress of Nephrology

The International Society of Nephrology and Latin American Society of Nephrology and Hypertension are planning the XVth International Congress of Nephrology and XIth Latin American Congress of Nephrology, May 2 to 6, 1999, in Buenos Aires, Argentina. A continuous medical education (CME) course will be offered in English and Spanish. Some of the themes include: Molecular Biology for the Clinician; Metabolic Bone Disease; Management of Urinary Tract Infections; Water, Acid-Base, and Electrolyte Disorders; Management of Hypertension in Renal Patients; Vascular Access Complications; Quality and Outcome of Dialysis; and Essential Hypertension. Topics for the main scientific program include: Hormones and the Kidney; Nonimmune Injury of the Kidney: and Renal Transplantation. Deadline for Abstracts is November 9, 1998. For young physicians and scientists who are submitting abstracts from developing countries, 120 ISN travel grants of $1000 (US) will be available. For more information, contact the Secretariat of the XV ICN, Ayacucho 937, 1° “G”, 1111 Buenos Aires, Argentina. Telephone: (+54 1) 812-1021; e-mail: bayfem@ibm.net.

17th Annual Meeting of the International Society for Blood Purification

The 17th Annual Meeting of the International Society of Blood Purification will be held in Prague, Czech Republic, October 7 to 9, 1999. Planned topics for symposia include: continuous renal therapies for acute renal failure, management of hypertension in end-stage renal disease, and current status and perspectives of plasma exchange. There will also be free communications and poster presentations. For more information, contact Dr. Vladimír Tesar, Division of Nephrology, 1st Department of Medicine, Charles University, U nemocnice 2, 128 08 Prague 2, Czech Republic. Telephone: (4202) 24962690; fax: (4202) 297932; e-mail: tesarv@beba.cesnet.cz; Internet: http://www.ISBP.org.