In hypertension or angina...
Control That’s Easy to Live With

**HIGH RATE OF SUCCESS IN AN NIH-SPONSORED STUDY**

83% of hypertensive patients—the highest percentage—remained on initial therapy with NORVASC® (amlodipine besylate) after 4 years; nearly all patients were on the 5-mg starting dose.

**LOW RATE OF DISCONTINUATION**

ONLY 1.5% of patients in placebo-controlled studies (n=1,730) discontinued therapy due to adverse effects.

**PROVEN SAFETY**

No negative inotropic effects at clinical doses in hemodynamic studies.*

No clinically significant effect on cardiac conduction or heart rate.

*Similar hemodynamic findings, however, have been observed with agents possessing significant negative inotropic effects.

Once-Daily NORVASC®

(amlodipine besylate)

Efficacy and safety that’s easy to live with.
In hypertension or angina, convenient once-daily dosing

- The usual starting dose is 5 mg in hypertension or angina
  - In hypertension, small, frail, 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
- The most common side effects are headache and edema

Once-Daily NORVASC®

Efficacy and Safety
That’s easy to live with

References
The Journal of the American Society of Nephrology

Frequency: One volume per year, beginning in January.

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For information on American Society of Nephrology membership, contact: Bronte Ward at (202) 857-1190.

Correspondence regarding editorial matters should be addressed to: C. Craig Tisher, M.D., J. Am. Soc. Nephrol., Division of Nephrology, Box 100224, 1600 SW Archer Road, University of Florida, Gainesville, Florida 32610.

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PhosLo\textsuperscript{\textregistered} is indicated for control of hyperphosphatemia in end-stage renal disease. Patients with higher-than-normal serum calcium levels should be closely monitored and their dose adjusted or terminated to bring levels to normal. 


Description: PhosLo\textsuperscript{\textregistered} (Calcium Acetate) is a phosphate binder that reduces the absorption of dietary phosphate. Each white round tablet contains 667 mg of calcium acetate (anhydrous) equal to 199 mg calcium, and 10 mg of the inert binder, polyethylene glycol 8000.

Contraindications: Patients with hypercalcemia.

Indications and Usage: PhosLo\textsuperscript{\textregistered} is indicated for the control of hyperphosphatemia in end-stage renal disease (ESRD) and does not promote aluminum absorption.

Warnings: Patients with ESRD may develop hypercalcemia when given calcium with meals. No other calcium supplements should be given concurrently with PhosLo\textsuperscript{\textregistered}. Serum calcium levels should be monitored when PhosLo\textsuperscript{\textregistered} therapy is started and periodically established. Safety in the elderly: No increased incidence of adverse reactions has been noted in patients over 65 years of age.

Precautions: Serum calcium and phosphate levels should be closely monitored. PhosLo\textsuperscript{\textregistered} should be taken with meals to insure the mixing of calcium with dietary phosphate.

Adverse Reactions: On occasion, patients have developed nausea while taking PhosLo\textsuperscript{\textregistered}, but the relationship of this adverse reaction to the drug is unclear as nausea often occurs in patients with end-stage renal disease. Mild hypercalcemia may occur in some patients, but it is easily controlled by reduction in dose or by temporarily discontinuing therapy.

Drug Interactions: The potential for hypercalcemia is increased if the patient takes other calcium supplements or calcitriol.

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Binds twice as much phosphate as equivalent amounts of calcium carbonate.\textsuperscript{1,2}

- Reimbursable under Medicaid and other state and private insurance programs.
- Tablets are swallowed, not chewed.
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Racial Inefficiency. Children and adults with chronic renal failure (CRF) tend to have decreased clearance as compared to normals. However, no mAb accumulation has been reported in children with CRF or end-stage renal disease (ESRD) due to current methods.

Reproductive Inefficiency - A reduction in mAb clearance has been noted in patients with severe liver disease. The mechanism for this impaired clearance is not known.

Adverse Effects of Nutropin (somatropin (GHRH origin)) for Injection on Growth Failure Due to Congenital Adrenal Hyperplasia

Two multicenter, randomized, controlled clinical trials were conducted to determine whether treatment with somatropin in children with congenital adrenal hyperplasia (CAH) for the treatment of growth failure and renal insufficiency could improve their growth rates and height deficits. One study was a double-blind, crossover design that involved open-label, randomization to Nutropin or placebo. The dose of Nutropin in both controlled studies was 0.25 mg/kg/day (35 IU/m²) administered as multiple subcutaneous injections. The data from the patients completing five years in the two controlled studies results in 62 children. The patients were monitored for a 78.6-month period or until the study was terminated or the study met the predetermined interim cutoff. The mean first-year growth rate was 0.33 cm/year for the Nutropin-treated patients, compared with a mass growth rate of 3.6 cm/year for placebo-treated control (p<0.0001). The mean second-year growth rate was 7.7 cm/year for the Nutropin-treated group, compared with 5.3 cm/year for controls (p<0.001). There was a significant increase in mean height at 18 months of age in the Nutropin-treated group compared with the placebo-treated group. In addition, the individual patients demonstrated an increase in growth hormone levels prior to treatment that were maintained after transplantation. These increases in growth hormone levels were associated with reduced protein catabolism and increased muscle mass.

INFORMATION FOR PATIENTS

When administering Nutropin to patients, the following instructions should be given, including a review of the contents of the Patient Information insert. This information is intended to aid in the safe and effective administration of the medication. It is not a substitute for all possible adverse effects or information.

If such adverse reactions do occur, avoid further administration of Nutropin and seek emergency medical treatment. In case of overdosage, consult emergency medical services.

Nutropin therapy should be discontinued if evidence of neoplasia develops.

PRECAUTIONS

Patients with a history of an intracranial lesion taking somatropin and/or somatropin receptor agonists should be monitored for signs or symptoms of intracranial hypertension. Patients with a history of a cerebrovascular accident should be monitored for signs and symptoms of intracranial hypertension.

Patients with a history of a cerebrovascular accident should be monitored for signs and symptoms of intracranial hypertension.

To reduce the risk of sudden death, patients should be monitored for evidence of intracranial hypertension.

Because of the potential for growth hormone excess, all patients should be monitored for signs and symptoms of hypothyroidism and hyperthyroidism.

Patients should be monitored for the possibility of abnormal glucose metabolism.

PATIENTS WITH A HISTORY OF A CEREBROVASCULAR ACCIDENT

Patients with a history of a cerebrovascular accident should be monitored for signs and symptoms of intracranial hypertension.

Patients should be monitored for the possibility of abnormal glucose metabolism.

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Patients should be monitored for the possibility of abnormal glucose metabolism.
Since board certification exams are given annually, the ASN will now offer its board review each year. The enormously successful 1996 course program has been expanded for 1997 to include an update for more senior nephrologists. Advanced workshops will be presented concurrently with the main review. This new format will allow you to shape your own course. Certified nephrologists may now obtain what information they need from the board review and choose to attend some or all of the advanced workshops. Highlights of the 1997 program include:

## Board Review:
- 48 hours of teaching and 48 continuing medical education (CME) credits
- Three full days, three half days (more time to see San Francisco)
- New topics: Pregnancy, Resistant Hypertension
- Audience Response Pads
- Two exams

## Advanced Workshops:
- 15 additional hours of teaching
- Ten 1½ - hour workshops with ten new topics
- Cutting-edge updates

### Course Director:
Robert G. Nurins, M.D.

### Faculty:
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- G. Appel, New York, N.Y.
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- H. Black, Chicago, Ill.
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### Enrollment is limited!
For information or to request a brochure, contact:

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The parenteral use of iron-carbohydrate complexes has resulted in anaphylactic-type reactions and death. Therefore, DEXFERRUM should not be administered to patients amenable to oral iron therapy.

†Data on file.
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Dexferm® (IRON DEXTRAN INJECTION, USP)

WARNING

THE PARENTERAL USE OF COMPLEXES OF IRON AND CARBOHYDRATES HAS RESULTED IN ABRASIVE EPISTAXIS. SLIGHT EPISTAXIS MIGHT OCCUR IN SOME PATIENTS. SUCH REACTIONS HAVE BEEN AScribed TO THE PHYSIOLOGICAL FORMS OF IRON, OR TO A LATERAL EXTREMITY TO TRANSPORT IRON WHICH IS SUBJECT TO PHYSIOLOGICAL CONTROL REPLEMENTS HEMOGLOBIN AND DEPLETED IRON STORES. DEXTRAN AND IRON IN SOLUTIONS OF SODIUM CITRATE CONTAIN A MINOR AMOUNT OF ALUMINUM, WHICH MAY BE AN ALLERGENIC REACTION IN A SMALL PERCENTAGE OF PATIENTS. IN DEXTRAN, THE IRON IS LIKELY TO BE THROUGH THE UREMIC PATHWAYS AFTER ADMINISTRATION OF IRON DEXTRAN.

WARNING: SEE BOXED WARNING

A risk of anaphylactic reactions occurs with the intramuscular injection of iron-carbohydrate complexes. Such complexes have been found under experimental conditions to produce anaphylactic shock when large doses or small doses injected repeatedly at the site of large injections. Doses, mals, and rabbits, and possibly in humans.

The long latent period between the injection of a potential carcinogenic and the appearance of a tumor makes it difficult to measure accurately the risk in man. There have, however, been several reports in the literature describing tumors at the injection site in humans who had previously received intramuscular injections of iron-carbohydrate complexes.

Large intravenous doses, such as used with total dose infusions (TDI), have been associated with an increased incidence of adverse effects. The adverse effects appear to be delayed in (1-2) days after treatment (types of injury) or by one of the following: symptoms or nekrosis, (e.g., mild to severe headache, nausea, vomiting, fever). The onset is usually 24-48 hours after administration and symptoms generally subside within 2-3 days. The symptoms are self-limited. The patient has not died. The patient's delayed reaction must be considered when evaluating the possibility of anaphylactic reactions due to Dextran.

The maximum 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 be used with caution during the period of iron loading when serum iron levels are elevated.
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Through
Microemulsion
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- Neoral provides increased bioavailability1 with adverse events* comparable to those of Sandimmune® when the dosage of the two drugs is adjusted to achieve the same cyclosporine blood trough concentrations.

- Routine monitoring is required and dosage adjustments may be necessary in both de novo patients and maintenance patients converted from Sandimmune to Neoral®.

- Neoral and Sandimmune are not bioequivalent and cannot be used interchangeably without physician supervision.

- Neoral offers an important option for the prevention of organ rejection in kidney, liver, and heart allogeneic transplant recipients.

Innovation Through Microemulsion

Neoral® cyclosporine capsules and oral solution for microemulsion

*The principal adverse reactions of cyclosporine therapy are renal dysfunction, tremor, hirsutism, hypertension, and gum hyperplasia.

*For de novo patients, start with the same Neoral dosage used with Sandimmune. For maintenance patients, conversion to Neoral is generally safe and well tolerated: Start with a simple 1:1 dosage conversion to Neoral (see boxed warning). Adjust the Neoral dosage to attain preconversion blood trough concentrations. The daily dosage of Neoral should always be given in two divided doses (b.i.d.).

Please see brief summary of prescribing information, boxed warning and reference for Neoral on the next page.
NEORAL® Soft Gelatin Capsules (cyclosporine capsules for microemulsion)

NEORAL® Oral Solution (cyclosporine oral solution for microemulsion)

Contraindications
Neoral® may be administered with other immunosuppressives agents. Increased susceptibility to infection and the possible development of lymphoma and other neoplasms may result from the degree of immunosuppression.

BRIEF SUMMARY: Please see pages 21-26 for full prescribing information.

WARNING: Only physicians experienced in immunosuppressive therapy and management of organ transplant patients should use this drug. The drug should be discontinued in facilities equipped with adequate laboratory and supportive medical resources. The physician responsible for management of transplant patients should be familiar with unusual complications of immunosuppressive therapy. Neoral® solutions are available in screw-capped units. The combination of Neoral® and other immunosuppressives may result in increased side effects due to overlapping toxicity and increased immunosuppressive effect. Neoral® may be administered with other immunosuppressives agents. Increased susceptibility to infection and the possible development of lymphoma and other neoplasms may result from the degree of immunosuppression.

Neoral® capsules contain microvasculature, ketconazole, and microsomal enzyme inhibitors. It is recommended that cyclosporine blood concentrations be monitored in patients taking Neoral® and that the physician take the necessary precautions to avoid excessive levels of cyclosporine as a result of drug interactions. A decrease in oral absorption may result from the concomitant use of other agents that are known to be potent inhibitors of cytochrome P-450 3A4. Neoral® capsules should be used with caution in patients with severe renal failure or in patients with concomitant use of other agents that may affect the absorption of cyclosporine.

Neoral® and Neoral® capsules contain microvasculature, ketconazole, and microsomal enzyme inhibitors. It is recommended that cyclosporine blood concentrations be monitored in patients taking Neoral® and that the physician take the necessary precautions to avoid excessive levels of cyclosporine as a result of drug interactions. A decrease in oral absorption may result from the concomitant use of other agents that are known to be potent inhibitors of cytochrome P-450 3A4. Neoral® capsules should be used with caution in patients with severe renal failure or in patients with concomitant use of other agents that may affect the absorption of cyclosporine.

The combination of Neoral® and other immunosuppressives may result in increased side effects due to overlapping toxicity and increased immunosuppressive effect. Neoral® may be administered with other immunosuppressives agents. Increased susceptibility to infection and the possible development of lymphoma and other neoplasms may result from the degree of immunosuppression.

Neoral® Soft Gelatin Capsules capsules contain microvasculature, and Neoral® Oral Solution contains microvasculature. It is recommended that cyclosporine blood concentrations be monitored in patients taking Neoral® and that the physician take the necessary precautions to avoid excessive levels of cyclosporine as a result of drug interactions. A decrease in oral absorption may result from the concomitant use of other agents that are known to be potent inhibitors of cytochrome P-450 3A4. Neoral® capsules should be used with caution in patients with severe renal failure or in patients with concomitant use of other agents that may affect the absorption of cyclosporine.

INDICATIONS AND USAGE: Neoral® is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allograft transplants. Neoral® has been used in combination with azathioprine and corticosteroids.

Neoral® is contraindicated in patients with a hypersensitivity to cyclosporine or to any of the ingredients of the formulation.

WARNING: (See boxed WARNING) Laborcynoprotein levels have been shown to be elevated in patients treated with Neoral®. The combination of Neoral® and other immunosuppressives may result in increased side effects due to overlapping toxicity and increased immunosuppressive effect. Neoral® may be administered with other immunosuppressives agents. Increased susceptibility to infection and the possible development of lymphoma and other neoplasms may result from the degree of immunosuppression.

Neoral® Soft Gelatin Capsules capsules contain microvasculature, and Neoral® Oral Solution contains microvasculature. It is recommended that cyclosporine blood concentrations be monitored in patients taking Neoral® and that the physician take the necessary precautions to avoid excessive levels of cyclosporine as a result of drug interactions. A decrease in oral absorption may result from the concomitant use of other agents that are known to be potent inhibitors of cytochrome P-450 3A4. Neoral® capsules should be used with caution in patients with severe renal failure or in patients with concomitant use of other agents that may affect the absorption of cyclosporine.

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In patients taking enalapril or felodipine ER alone...

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**NEW LEXXEL 5-15 mg**

**ENALAPRIL MALEATE + FELODIPINE ER**

**ONE TABLET • ONCE A DAY**

**USE IN PREGNANCY:** When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, LEXXEL should be discontinued as soon as possible. (See WARNINGS, Fetal/Neonatal Morbidity and Mortality.)

Angioedema may occur at any time during treatment. Discontinue LEXXEL at the first sign of angioedema and treat appropriately. (See WARNINGS, Angioedema.)

In clinical trials, the most common adverse events were headache, dizziness, and peripheral edema.

**Before prescribing LEXXEL, please see brief summary of Prescribing Information on adjacent page.**

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LEXCEL® 5-5 mg
(WALPHATE, WALPUPHATE-9MMOLES ON TABLETS)

Before prescribing, please read the prescribing information.

USYNOPSIS
When used in combination for the treatment of hypertension, ACE inhibitors and calcium channel blockers, the potential benefits of the combination should be considered in the context of the individual patient's needs.

USES
LEXCEL is indicated for the treatment of hypertension. It is not indicated for the initial treatment of hypertension in patients with severe (NYHA class IV) heart failure.

INDICATIONS AND USAGE
LEXCEL is indicated for the treatment of hypertension. It is not indicated for the initial treatment of hypertension in patients with severe (NYHA class IV) heart failure.

CONTRAINDICATIONS
LEXCEL is contraindicated in patients who are hypersensitive to any component of the product. Because of the antihypertensive component, LEXCEL is contraindicated in patients with impaired renal function.

WARNINGS
Lexcel may cause hypotension, which may be additive to that of other agents that lower blood pressure. Therefore, it is important to monitor blood pressure in patients taking LEXCEL.

PRECAUTIONS
Consult a physician before using LEXCEL in patients with cardiac disease, renal disease, liver disease, or a history of drug abuse.

Available at http://www.merck.com/packaging/lexcel.pdf

Patient Instructions: Read the enclosed patient instructions carefully before using this product.

Adverse Events: The most common adverse events reported in clinical trials were:

1. Nausea
2. Diarrhea
3. Headache
4. Asthenia

In rare cases, patients may experience adverse events such as:

1. Elevated liver enzymes
2. Hypokalemia
3. Hyperkalemia

If any of these adverse events occur, please contact your healthcare provider immediately.

Special Populations: LEXCEL is generally safe for use in patients with renal impairment, but close monitoring is recommended.

Hypotension: Caution is advised in patients with a history of hypotension.

-seasonal and non-seasonal mammals

References:

Additional information: For more detailed information, please refer to the full Prescribing Information and Package Insert.
LEXIEL® (Enalapril Maleate-Felodipine ER) Tablets

Other clinical adverse events considered related (possibly, probably or definitely) to treatment with enalapril-felodipine ER that occurred with an incidence of less than one percent in the placebo-controlled, double-blind trial are listed below. These events are listed in order of decreasing frequency within each category. Body as a Whole: Syncope, facial flushing, orthostatic effects, chest pain, epigastric pain. Cardiovascular: Hypertension, bradycardia, premature ventricular contraction, increased blood pressure. Digestive: Dry mouth, constipation, dyspepsia, flatulence, acid regurgitation, vomiting, diarrhea, nausea, anal incontinence, Metabolic: Gout, Hyperlipidemia, Cough, Nausea, sleepiness, dysuria, paresthesia, depression, anxiety. Skin: Rash, angioedema, pruritus, alopecia, dry skin. Special Senses: Increased intracranial pressure, Dizziness, Impotence, hot flashes.

Other infrequently reported adverse events were seen in clinical trials with enalapril-felodipine ER (causal relationship unknown). These included: Body as a Whole: Abdominal pain, fever, Dyspepsia: Dental pain. Metabolic: Increased ALT and AST. Hematologic: Anemia, Neutropenia, Leukopenia (in some patients with changes in platelet counts). Respiratory: Upper respiratory infection, sinusitis, pharyngitis, bronchitis, nasal congestion, influenza, sinus disorder. Special Senses: Conjunctivitis, keratitis, Proctitis, edema, urinary tract infection.

Enalapril Maleate: Other adverse events that have been reported with enalapril, without regard to causality, are listed below.

- Angioedema: Angioedema has been reported in patients receiving enalapril maleate. In infrequent cases, angioedema associated with edema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients receiving enalapril. If angioedema occurs, treatment with LEXIEL should be discontinued and appropriate therapy instituted immediately. (See WARNINGS, Pancreatitis).
- Abnormal liver function tests. Increases in liver enzyme levels have been reported rarely. (See WARNINGS, Pancreatitis).

Other clinical adverse events considered related (possibly, probably or definitely) to treatment with felodipine ER that occurred with an incidence of less than one percent in the placebo-controlled, double-blind trial are listed below. These events are listed in order of decreasing frequency within each category. Cardiovascular: Cough, dyspnea, edema, angina, extrasystoles, increases in blood pressure, palpitations, flushing, flushing, hypotension, hypertensive crisis, tachycardia, bradycardia, atrial fibrillation, angina pectoris. Gastrointestinal: Nausea, vomiting, flatulence, diarrhea, dyspepsia, anorexia, constipation, dry mouth, constipation, dyspepsia, flatulence, acid regurgitation, vomiting, diarrhea, nausea, anal incontinence, Metabolic: Gout, Hyperlipidemia, Cough, Nausea, sleepiness, dysuria, paresthesia, depression, anxiety. Skin: Rash, angioedema, pruritus, alopecia, dry skin. Special Senses: Increased intracranial pressure, Dizziness, Impotence, hot flashes.

Other infrequently reported adverse events were seen in clinical trials with enalapril-felodipine ER (causal relationship unknown). These included:

- Upper respiratory infection, sinusitis, pharyngitis, bronchitis, nasal congestion, influenza, sinus disorder. Special Senses: Conjunctivitis, keratitis, Proctitis, edema, urinary tract infection.

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For documented iron-deficiency anemia not amenable to oral therapy

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The parenteral use of complexes of iron and carbohydrates has resulted in anaphylactic-type reactions. Deaths associated with such administration have been reported. Therefore, INFeD® 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.

Please see complete prescribing information under WARNINGS, PRECAUTIONS and ADVERSE REACTIONS including boxed WARNING for a complete listing of side effects.

*A study of 48 recombinant human erythropoietin-treated patients who were randomized to 4 groups to receive 4 different oral iron preparations demonstrated the following: In the short term oral iron was adequate to maintain iron status, but the downward trend in ferritin in 3 of the 4 groups indicated that eventually intravenous iron dextran would likely be required.

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**For documented iron-deficiency anemia not amenable to oral therapy**

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Replaces Iron Rapidly
**IMMUNE (IRON DEXTREN INJECTION, USP)**

**DESCRIPTION:** iron dextran injection, USP, is a dark brown, slightly viscous, cloudy, lactic acid resistant system of iron and dextran used for intravenous or intramuscular use.

The iron dextran complex has an average apparent molecular weight of 160,000.

The iron dextran complex is distributed throughout the body, being removed from the body at an unknown rate. The distribution time is dependent on the iron content of the iron dextran complex.

**INDICATIONS AND USES:** Intravenous or intramuscular injections of iron dextran are indicated for treatment of patients with normal iron stores who are administered iron in doses of 250 mg or less as single injections.

**CONTRAINDICATIONS AND PRECAUTIONS:** iron dextran is contraindicated in patients allergic to iron or dextran.

**ADVERSE REACTIONS:** iron dextran has been shown to cause a delayed-type hypersensitivity reaction in patients allergic to dextran or iron.

**DOSAGE AND ADMINISTRATION:** Iron dextran is administered intravenously or intramuscularly.

**DETECTION:** Iron dextran is detectable in the serum for several days after injection.

**PATIENT MANAGEMENT:** Iron dextran should be used only in patients in whom the injection is indicated.

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Recent MD/PhD graduates interested in nephrology research at Stanford are invited to apply for an NIH Training Grant fellowship to begin July 1, 1998. For information write: Rex Jamison, M.D., Division of Nephrology, Stanford University School of Medicine, Stanford, CA 94305. Phone: 415-723-6247; Fax: 415-723-7917; email: rjamison@leland.stanford.edu. Stanford is committed to increasing representation of women and members of minority groups in residency and fellowship training and particularly encourages such applications.

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At your request, your Abbott Renal Care representative can review current opinion and practices regarding compliance and high peak serum levels in calcitriol therapy. Your representative also has details of upcoming symposia and other events that will further broaden the information base available to you and your staff.

BRIEF SUMMARY

Calcitriol Injection

1 mcg and 2 mcg/mL

INDICATIONS AND USAGE
Calcitriol (calcitriol injection) is indicated in the management of hyperparathyroidism in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone levels. Reduction of PTH has been shown to result in an improvement in renal osteodystrophy.

CONTRAINDICATIONS
Calcitriol (calcitriol injection) should not be given to patients with hypercalcemia or evidence of vitamin D toxicity.

WARNINGS
Serum calcium is the most potent metabolite of vitamin D available, vitamin D and its derivatives should be withheld during treatment.

A non-aluminum phosphate-binding compound should be used to control serum phosphorus levels in patients undergoing dialysis.

Overdosage of any form of vitamin D is dangerous (see also OVERDOSE). Progressive hypercalcemia due to overdose of vitamin D and its metabolites may be so severe as to require emergency attention. Chronic hypercalcemia can lead to generalized vascular calcification, nephrocalcinosis and other soft-tissue calcification. The serum calcium times phosphate (Ca x P) product should not be allowed to exceed 70. Radiographic evaluation of suspect anatomic regions may be useful in the early detection of this condition.

PRECAUTIONS:

1. General
Excessive dosages of Calcitriol (calcitriol injection) induce hypercalcemia and in some instances hypercalcemia, therefore, early in treatment during dosage adjustment, serum calcium and phosphorus should be determined at least twice weekly. Should hypercalcemia develop, the drug should be discontinued immediately.

Calcitriol should be given cautiously to patients on dialysis, because hypercalcemia in such patients may precipitate cardiac arrhythmias.

2. Information for the Patient
The patient and his or her parents should be informed about adherence to instructions about diet and calcium supplementation and avoidance of the use of unapproved non-prescription drugs, including magnesium-containing antacids. Patients should also be carefully informed about the symptoms of hypercalcemia (see ADVERSE REACTIONS).

3. Essential Laboratory Tests
Serum calcium, phosphorus, magnesium and alkaline phosphatase and 24-hour urinary calcium and phosphorus should be determined periodically. During the initial phase of the medication, serum calcium and phosphorus should be determined more frequently (twice weekly).

4. Drug Interactions
Magnesium-containing antacid and Calcitriol should not be used concomitantly, because such use may lead to the development of hyperparathyroidism.

5. Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Calcitriol (calcitriol injection). There was no evidence of mutagenicity as studied by the Ames Method. No significant effects of calcitriol on fertility were reported using oral Calcitriol.

6. Use in Pregnancy: Pregnancy Category C
Calcitriol given orally has been reported to be teratogenic in rabbits when given in doses 4 and 15 times the dosage recommended for human use.

All 15 litters in 3 litters at these doses showed external and skeletal abnormalities. However, none of the other 23 litters (116 litters) showed significant abnormalities compared with controls.

Teratology studies in rats showed no evidence of teratogenic potential. There are no adequate and well-controlled studies in pregnant women. Calcitriol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

7. Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from calcitriol, 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.

8. Pediatric Use
Safety and efficacy of Calcitriol in children have not been established.

ADVERSE REACTIONS
Adverse effects of Calcitriol (calcitriol injection) are, in general, similar to those encountered with excessive vitamin D intake. The early and late signs and symptoms of vitamin D intoxication associated with Calcitriol include:

1. Early
Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain and metallic taste.

2. Late
Polyuria, polydipsia, anorexia, weight loss, nocturia, conjunctivitis (calcific), pancreatitis, phosphenes, rickets, myalgia, arthralgia, hypercalcemia, elevated BUN, albuminuria, hypercholesterolemia, elevated SGOT and SGPT, ectopic calcification, hypercalciuria, cardiac arrhythmias and, rarely, overt psychosis.

Occasional mild pain on injection has been observed.

OVERDOSE
Administration of Calcitriol (calcitriol injection) to patients in excess of their requirements can cause hypercalcemia, hypercalciuria and hyperphosphatemia. High intake of calcium and phosphate concomitantly with Calcitriol may lead to similar abnormalities.

1. Treatment of Hypercalcemia and Overdose in Patients on Hemodialysis
General treatment of hypercalcemia (greater than 1 mg/dL above the upper limit of normal range) consists of immediate discontinuation of Calcitriol therapy, institution of a low calcium diet and withdrawal of calcium supplements. Serum calcium levels should be determined daily until normocalcemia ensures. Hypercalcemia usually resolves in two to seven days. When serum calcium levels have returned to within normal limits, Calcitriol therapy may be reinstituted at a dose 5.5 mcg less than prior therapy. Serum calcium levels should be obtained at least twice weekly after all dosage changes.

 Persistent or markedly elevated serum calcium levels may be corrected by dialysis against a calcium-free dialysate.

2. Treatment of Accidental Overdosage of Calcitriol Injection
The treatment of acute accidental overdose of Calcitriol should consist of general supportive measures. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and low calcium diet are also indicated in accidental overdose. Due to the relatively short duration of the pharmacological action of calcitriol, further measures are probably unnecessary. Should, however, persistent and markedly elevated serum calcium levels occur, there are a variety of therapeutic alternatives which may be considered depending on the patient's underlying condition. These include the use of drugs such as phosphates and corticosteroids as well as measures to induce an appropriate forced diuresis. The use of peritoneal dialysis against a calcium-free dialysate has also been reported.

SUPPLIED
Calcitriol (calcitriol injection) is supplied in 1 mL ampuls containing 1 mcg (Lot No. 1200) and 2 mcg (Lot No. 1210).

Protect from light.

Store at controlled room temperature 15° to 30°C (59° to 86°F).

Caution: Federal (USA) law prohibits dispensing without prescription.

See complete Professional Use Information before prescribing.

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