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=1730) 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, 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
- The most common side effects are headache and edema

Once-Daily NORVASC® (amlodipine besylate)

Efficacy and Safety That’s Easy to Live With

References
1. Newton, D.C. Arzneimittel 1993; 2:119-122
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A high quality, very consistent, and clinically tested intravenous iron from a leader in quality parenterals.

The safety and efficacy of DEXFERRUM have been established with ESRD patients on Epoetin alfa in controlled, multi-center trials.

American Regent Laboratories, known for quality parenterals throughout the U.S., supports the dialysis community with services such as a reimbursement hotline and a patient assistance program. Our clinical specialists are dedicated to helping you achieve optimum patient outcomes.

Now you can prescribe injectable iron with a new measure of confidence. Because with DEXFERRUM, the connection between quality care and clinical results is virtually inseparable.

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.
DEXFERRUM®
(IRON DEXTRAN INJECTION, USP)
*The quality choice.*

Please see prescribing information on the following page.
DESCRIPTION: DEXFERRUM® (IRON DEXTRAN INJECTION, USP) is a dark brown, slightly viscous sterile liquid composed of iron (III) chloride and sodium citrate. It is available in 50 mg elemental iron as an iron dextran complex. Sodium citrate may or may be added to tonicity. Water for injection is added to adjust to 5%. Iron dextran is not immediately available for administration. The iron dextran complex is not dissociated when in solution.

DOSAGE AND ADMINISTRATION: Intravenous administration of iron dextran complex can be used when oral iron therapy is not possible or when iron absorption is inadequate. Iron dextran is well absorbed after intramuscular or intravenous administration. The concentration of iron in the serum for 24 hours after injection is approximately 25% of the dose administered. While the maximum effective concentration of iron in the serum is not known, it is recommended that the serum iron concentration not exceed 300 mcg/ml. Serum iron concentration is not an indication of the effectiveness of parenteral iron therapy. Iron dextran is a potential carcinogen. It is not effective for iron-refractory anemias.

DOSAGE FORMS: DEXFERRUM® (IRON DEXTRAN INJECTION, USP) is available in 50 mg elemental iron/mL in 5 ml vials. The contents of one vial should be diluted with 50 mL of normal saline or 5% dextrose in water for intravenous administration. The intramuscular dose is 0.5-1.0 ml.

WARNINGS: If the intravenous injection is continued beyond the recommended time, or if the intravenous line is occluded or becomes less than 1 mm in diameter, the reaction may be intensified or prolonged. If the intravenous line is occluded or becomes less than 1 mm in diameter, the reaction may be intensified or prolonged. The intravenous line should be flushed with 50 mL of normal saline or 5% dextrose in water before administration of the next dose. If the intravenous line is occluded or becomes less than 1 mm in diameter, the reaction may be intensified or prolonged.

SIDE EFFECTS: The principal side effects of iron dextran therapy are headache and fever. Headache and fever are usually mild and are dose-limiting. Fever is generally reduced by the concomitant use of antibiotics.

CONTRAINDICATIONS: The following were observed in animal studies: Iron dextran is not effective for iron-refractory anemias. In the absence of clinical evidence, it is not known whether iron dextran is effective for iron-refractory anemias. Therefore, caution should be exercised in the use of iron dextran in patients with iron-refractory anemias. Iron dextran is not effective for iron-refractory anemias.

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This bacterium can cost a life.\(^1,5\)

**This Blue catheter can save it.**

The hemodialysis patient population has a high incidence of catheter-related bacteremias.\(^2\) Overall, central venous catheter-related nosocomial infections occur at a rate of 3\% to 12\%,\(^1\) with a 10-20% fatality rate.\(^1\) Fortunately, there is a catheter that can help minimize this risk and its associated costs in your hospital.

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For documented iron-deficiency anemia not amenable to oral therapy

A CRUCIAL LINK
INFeD® AND EPO

in the treatment of iron-deficiency anemia for most ESRD patients$^1$
INFeD® and EPO for target HCT range of 30% to 36%5,6

- Treatment is currently targeted to a hematocrit range of 30% to 36%6

INFeD® for effective erythropoiesis

- Erythropoiesis can rapidly mobilize iron reserves and deplete even ample iron stores1

INFeD® for rapid iron repletion

- IV iron should be considered for all patients with low iron stores requiring a rapid EPO response1,4
- In dialysis patients receiving EPO: “The efficacy of oral iron is variable in these patients, and many require the use of intravenous iron dextran to maintain adequate iron levels…”8

INFeD® evaluated for safety in hemodialysis patients

- After reviewing the charts of 573 patients treated with INFeD® from four hemodialysis centers, Fishbane et al concluded: “We found serious adverse reactions with IVFe in hemodialysis patients to be uncommon.”8

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 46 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.

For documented iron-deficiency anemia not amenable to oral therapy

INFeD®
Iron Dextran Injection, USP 50 mg/mL
Replaces Iron Rapidly
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• It is assumed that all clinical investigation described in the manuscript was conducted in accordance with the guidelines proposed in the Declaration of Helsinki. Document in the manuscript that informed consent was obtained.

• It is assumed that all animal experimentation described in the manuscript was conducted in accord with the NIH Guide for the Care and Use of Laboratory Animals or the equivalent, and the manuscript should contain a statement to that effect.

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Legends should state degree of magnification or scale bars should be used on the photograph.

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- Supplies the essential amount of iron for successful Epogen® therapy
- Reduces the need for and risks associated with IV iron
- Delivers liquid iron to the site of optimal absorption for enhanced GI tolerability and excellent patient compliance

The most solid choice is liquid

Recommend the most widely prescribed oral iron supplement...now formulated to meet the needs of those who need iron most.

Chromagen Forte

The strength of liquid iron in a soft gelcap

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Based on IMS National Prescription Audit, June 1996.
Introducing Chromagen Forte Liquid-Iron Gelcaps

- Contains 151 mg of elemental iron—the most elemental iron available in an oral hematinic today¹
- Supplies the essential amount of iron for successful Epogen® therapy² ³
- Reduces the need for and risks associated with IV iron⁵
- Delivers liquid iron to the site of optimal absorption for enhanced GI tolerability and excellent patient compliance

The strength of liquid iron in a soft gelcap

Recommend the most widely prescribed oral iron supplement⁶...now formulated to meet the needs of those who need iron most.

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² Based on IMS National Prescription Audit, June 1996.
**DISCUSSION:**

Iron deficiency and homocysteine deficiency are contraindications to iron therapy. Folic acid is contraindicated in patients with pernicious anemia (see PRECAUTIONS).

**SIDE EFFECTS:**

Average capsule doses in sensitive individuals or excessive dosage may cause nausea, skin rash, vomiting, diarrhea, precordial pain, or flushing of the face and extremities.

**PRECAUTIONS:**

Folic acid should not be prescribed until the diagnosis of pernicious anemia has been eliminated, since it can alleviate the hematological manifestations, while allowing neurological damage to continue undetected.  

**DOSEAGE AND ADMINISTRATION:**

Usual adult dose is 1 soft gelatin capsule daily.

**HOW SUPPLIED:**

Capsules: NDC 0281-0282-53, Bottle of 100

Capsules: NDC 0281-0282-56, Bottle of 500

CAUTION: Federal law prohibits dispensing without prescription.

**REFERENCES:**


**BIBLIOGRAPHY:**


**DESCRIPTION:**

Chromagen® Forte Soft Gelatin Capsules contains ferrous fumarate USP, 460 mg (151 mg elemental iron), ascorbic acid USP, 60 mg, folic acid USP, 1 mg, and cyanocobalamin USP, 10 mcg.

**DISCUSSION:**

The amount of elemental iron and the absorption of the iron components of commercial iron preparations vary widely. It is further established that certain "accessory components" may be included to enhance absorption and utilization of iron. Chromagen® Forte Capsules are formulated to provide the essential factors for a complete, versatile hematonic.

**ACTIVITIES**

HIGH ELEMENTAL IRON CONTENT: Ferrous fumarate, used in Chromagen® Forte Capsules, is an organic iron complex which has the highest elemental iron content of any hematinic salt - 33%. This compares with 20% for ferrous sulfate (hepathydrate) and 13% for ferrous gluconate. Chromagen® Forte contains 151 mg of elemental iron.

MORE COMPLETE ABSORPTION: It has been repeatedly shown that ascorbic acid, when given in sufficient amounts, can increase the absorption of ferrous iron from the gastrointestinal tract.  

The absorption-promoting effect is mainly due to the reducing action of ascorbic acid within the gastrointestinal lumen, which helps to prevent or delay the formation of insoluble or less dissociated iron compounds.  

PROMOTES MOVEMENT OF PLASMA IRON: Ascorbic acid also plays an important role in the movement of plasma iron to storage depots in the tissues. It also is evident that ascorbic acid improves iron utilization, presumably as a reducing agent of its reducing action, and some evidence that it may have a direct effect upon erythropoesis.

EXCELLENT ORAL TOLERATION: Ferrous fumarate is used in Chromagen® Forte Capsules because it is less likely to cause the gastric disturbances so often associated with oral iron therapy. Ferrous fumarate has a low ionization constant and high solubility in the entire pH range of the gastrointestinal tract. It does not precipitate proteins or have the astringency of more ionizable forms of iron, and does not interfere with proteolytic or diastatic activities of the digestive system. Because of excellent oral tolerance, Chromagen® Forte Capsules can usually be administered between meals when iron absorption is maximal.

FOLIC ACID SUPPLEMENTATION: The use of supplemental folic acid may be indicated in patients with increased requirements for this vitamin, such as iron deficiency anemia. Folic acid administration may reduce the risk of neural tube defects in the developing fetus. Folic acid has also been shown to reduce circulating homocysteine levels in the blood. 

Folate as 5-methyltetrahydrofolic acid and as folic acid is involved in the remethylation reaction of homocysteine to methionine. Elevated homocysteine plasma levels are associated with increased risk of preeclampsia, neural tube defects, myoccardial infarction and atherosclerosis.

TOXICITY: Ferrous fumarate was found to be the least toxic of three popular oral iron salts, with an oral LD₅₀ of 630 mg/kg. In the same report, the LD₅₀ of ferrous gluconate was reported to be 320 mg/kg and ferrous sulfate 230 mg/kg.

INDICATIONS:

For the treatment of all anemias responsive to iron therapy, such as hypochromic anemia associated with pregnancy, chronic or acute blood loss, dietary restriction, metabolic disease and post-surgical convalescence.

CONTRAINDICATIONS:

Hemochromatosis and hemosiderosis are contraindications to iron therapy. Folic acid is contraindicated in patients with pernicious anemia (see PRECAUTIONS).
Unique Cyclosporine Formulation

- Neoral® demonstrates intrasubject variability of drug exposure (%CV) [measured by comparing the area under the concentration-vs.-time curve] in renal transplant recipients of 9% to 21% compared to 19% to 26% for Sandimmune® (cyclosporine).
- Neoral provides increased bioavailability* 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.
Occasionally Dmg in treatment pressure should be used. Other Dmg in the treatment of NeoraP capsules for microemulsion.

**SUMMARY:**

Cyclosporine, the active ingredient of NeoraP, can cause nephrotoxicity and nephropathy when used in high doses. It is important to maintain Dmg blood levels to be elevated during cyclosporine therapy. In renal transplant patients, Dmg blood levels do not indicate rejection, and each patient should be fully evaluated before dosage adjustment.

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

**CONTRAINDICATIONS:** NeoraP is contraindicated in patients with a hypersensitivity to cyclosporine or to any of the ingredients. NeoraP should not be used in patients with active infections and should be used with caution in patients with pre-existing severe liver disease.

**WARNINGS:** (See boxed WARNING.)

Cyclosporine, the active ingredient of NeoraP, can cause nephrotoxicity and nephropathy when used in high doses. It is important to maintain Dmg blood levels to be elevated during cyclosporine therapy. In renal transplant patients, Dmg blood levels do not indicate rejection, and each patient should be fully evaluated before dosage adjustment.

Based on the historical Sandimmune experience with oral solution, nephrotoxicity associated with cyclosporine has been noted in 25% of cases of renal transplantation, 36% of cases of cardiac transplantation, and 37% of cases of liver transplantation. In patients receiving cyclosporine, the most frequent cause of renal dysfunction is severe renal failure due to cyclosporine. For a high trough concentration of Cyclosporin A in the pre-operative evaluations of BUN and creatinine at a range of 35-45 mg/dL and 2.0-2.5 mg/dL respectively.

These electrolytes and cyclosporine doses reduce the risk of nephrotoxicity. The maintenance of cyclosporine concentration is required for evidence of these findings. These electrolytes and cyclosporine doses reduce the risk of nephrotoxicity.

After specific diagnostic criteria which reliably differentiate renal graft rejection from drug toxicity have not been found, a reliable method for determining graft rejection in cyclosporine recipients is the absence of rejection-related changes, the GFR being the best indicator. For patients receiving cyclosporine, the most frequent cause of renal dysfunction is severe renal failure due to cyclosporine. The measurement of cyclosporine concentration is required for evidence of these findings.

As in patients receiving other immunosuppressants, those patients receiving cyclosporine are at increased risk for development of lymphomas and other malignancies, particularly those of the skin. The increased risk appears related to the intensity and duration of immunosuppression rather than to the use of specific agents. Because of the danger of over-suppression of the immune system resulting in increased risk of infection or malignancy, a treatment regimen containing multiple immunosuppressants should be used with caution.

There have been reports of convulsions in adult and pediatric patients receiving cyclosporine, particularly in combination with high dose prednisone.

Care should be taken in using cyclosporine with nephrotoxic drugs. Because NeoraP is not bioavailable to Sandimmune, conversion from NeoraP to Sandimmune using a 1:1 ratio (mg/mg) is not recommended. NeoraP for oral solution should be used with caution in patients with pre-existing liver disease.

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MIDWEST NEPHROLOGIST

BC/BE Nephrologist needed to join Carle Clinic Association in Urbana, IL, by July of 1997. Carle Clinic is a 300 physician owned and operated multi-specialty group practice in Central Illinois. Practice entails general and consultative nephrology, hypertension, acute/chronic hemodialysis and CAPD. Extensive fringe benefits include partnership and income sharing plan after two years; available academic appointment with the University of Illinois; professional liability, health, life, and disability insurance; excellent vacation and meeting time. Send CV to: Tamara T. Mitchell, M.D., Medical Director, Carle Clinic Association, 602 W. University Ave., Urbana, IL 61801. Fax: 217-383-3163, or call: (800) 436-3095.

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Editorial Profile: Journal of the American Society of Nephrology publishes original articles of high quality and relevant to the broad field of nephrology. Nephrology is an alliance of scientists and physicians who seek to understand the function of the kidneys and the means to improve the medical care of individuals with renal disease. Subjects appropriate for the journal include: clinical nephrology, renal and epithelial physiology, renal pathophysiology, body fluid, electrolyte and acid-base metabolism, hypertension, dialysis, and renal transplantation.

Closing Dates: The deadline for ad placement is the 5th of the month prior to the month of publication.

Printing Requirements: Negatives, mechanicals or camera-ready copy. If you would like us to typeset your ad, there is an additional fee, as follows: 1/8 page-$25, 1/4 page-$45, 1/2 page-$60, 1 page-$85.

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