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

**References**
There's More To EPOGEN® (Epoetin alfa) Than Epoetin Alfa.

When you specify EPOGEN® (Epoetin alfa), you get more than a product. You also get a comprehensive support system. That’s important, because the depth and quality of professional support is a significant element in long-term clinical success.

EPOGEN® support encompasses the Amgen Reimbursement Hotline, the Amgen SAFETY NET® Program, Professional Services, Professional Education Programs, and Clinical Support Services. Your Amgen Professional Sales Representative can tell you more about the ways these programs can satisfy your needs.

There simply is no comparable source of professional support. That’s not surprising, because EPOGEN® is a lot more than just a drug. It’s a way of life.

For more information, please call 1-800-77-AMGEN.
In Your Adult Predialysis and Dialysis Patients...

HELP ERADICATE HEPATITIS B

Use the only vaccine with a concentrated 40 mcg/mL dose precisely formulated for predialysis and dialysis patients

RECOMBIVAX HB
[HBV Vaccine [Recombinant]]

The Vision and Precision to Help End Hepatitis B

RECOMBIVAX HB is contraindicated in the presence of hypersensitivity to yeast or to any component of the vaccine. Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine. RECOMBIVAX HB Dialysis Formulation (40 mcg/mL) is intended only for adult predialysis/dialysis patients. A booster dose or revaccination may be considered if the anti-HBs level is less than 10 mIU/mL 1–2 months after the third dose. Please read the Brief Summary of the Prescribing Information accompanying this advertisement.
BRIEF SUMMARY

RECOMBIVAX HB®
HEPATITIS B VACCINE (RECOMBINANT)

Please read the full Prescribing Information for complete details.

INDICATIONS AND USAGE
RECOMBIVAX HB is indicated for vaccination against infection caused by all known subtypes of hepatitis B virus. RECOMBIVAX HB Dialysis Formulation is indicated for vaccination of adult predialysis and dialysis patients against infection caused by all known subtypes of hepatitis B virus.

CONTRAINDICATIONS
Hypersensitivity to yeast or any component of the vaccine.

WARNINGS
Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine (see CONTRAINDICATIONS).

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis B in such patients.

PRECAUTIONS
General
As with any percutaneous vaccine, epinephrine should be available for immediate use should an anaphylactoid reaction occur.

Any serious active infection is reason for delaying use of the vaccine except when in the opinion of the physician, withholding the vaccine entails a greater risk.

Caution and appropriate care should be exercised in administering the vaccine to individuals with severely compromised cardiopulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Pregnancy
Pregnancy Category C: Animal reproduction studies have not been conducted with the vaccine. It is also not known whether the vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. The vaccine should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether the vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when the vaccine is administered to a nursing woman.

Pediatric Use
RECOMBIVAX HB has been shown to be usually well-tolerated and highly immunogenic in infants and children of all ages. Newborns also respond well; maternally transferred antibodies do not interfere with the active immune response to the vaccine. See DOSAGE AND ADMINISTRATION in full Prescribing Information for recommended pediatric dosage and for recommended dosage for infants born to HBsAg positive mothers.

The safety and effectiveness of RECOMBIVAX HB Dialysis Formulation in children have not been established.

ADVERSE REACTIONS
RECOMBIVAX HB and RECOMBIVAX HB Dialysis Formulation are generally well-tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. No adverse experiences were reported during clinical trials which could be related to changes in the titers of antibodies to yeast. As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

Incidence Less Than 1% of Injections

BODY AS A WHOLE
Sweating; achiness; sensation of warmth; lightheadedness; chills; and flushing

DIGESTIVE SYSTEM
Vomiting; abdominal pains/cramps; dyspepsia; and diminished appetite

RESPIRATORY SYSTEM
Rhinitis; influenza; and cough

NERVOUS SYSTEM
Vertigo/dizziness; and paresthesia

INTEGUMENTARY SYSTEM
Pruritus; rash (non-specified); angioedema; and urticaria

MUSCULOSKELETAL SYSTEM
Arthralgia including monarticular; myalgia; back pain; neck pain; shoulder pain; and neck stiffness

HEMICLYMPHATIC SYSTEM
Lymphadenopathy

PSYCHIATRIC/Behavioral
Insomnia/disturbed sleep

SPECIAL SENSES
Earache

UROGENITAL SYSTEM
Dysuria

CARDIOVASCULAR SYSTEM
Hypotension

Marketed Experience
The following additional adverse reactions have been reported with use of the marketed vaccine. In many instances, the relationship to the vaccine was unclear.

Hypersensitivity
Anaphylaxis and symptoms of immediate hypersensitivity reactions including rash, pruritus, urticaria, edema, angioedema, dyspnea, chest discomfort, bronchial spasm, palpitation, or symptoms consistent with a hypotensive episode have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including; arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum (see WARNINGS and PRECAUTIONS).

Digestive System
Elevation of liver enzymes; constipation.

Nervous System
Guillain-Barré Syndrome; multiple sclerosis; myelitis including transverse myelitis; peripheral neuropathy including Bell's Palay; radiculopathy; herpes zoster; migraine; muscle weakness; hypesthesia.

Integumentary System
Stevens-Johnson Syndrome; petechiae.

Musculoskeletal System
Arthritis.

Hematologic
Increased erythrocyte sedimentation rate; thrombocytopenia.

Immune System
Lupus-like syndrome.

Psychiatric/Behavioral
Irritability; agitation; somnolence.

Special Senses
Optic neuritis; tinnitus; conjunctivitis; visual disturbances.

Cardiovascular System
Syncope, tachycardia.

The following adverse reaction has been reported with another Hepatitis B Vaccine (Recombimant) but not with RECOMBIVAX HB: keratitis.
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® therapy²-⁴
- 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

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

Rx CHROMAGEN® FORTE

The strength of liquid iron in a soft gelcap

¹Based on a nationwide survey of nephrologists. Data on file, Savage Laboratories.
²Epogen (epoetin alfa) is a registered trademark of Amgen Inc.
³Based on IMS National Prescription Audit, December 1996.
DESCRIPTION

CONTENTS: Each brown soft gelatin capsule contains: ferrous fumarate USP, 460 mg (151 mg elemental iron), ascorbic acid USP, 60 mg, folic acid USP, 1 mg, 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 hematique.

ACTIONS

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 hematique salt - 33%. This compares with 20% for ferrous sulfate (hepathydrate) and 13% for ferrous gluconate. 1,2 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 2,4,5,6,7,8. 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 ferric compounds. 3

PROMOTES MOVEMENT OF PLASMA IRON: Ascorbic acid also plays an important role in the movement of plasma iron to storage depots in the tissues. 10 The action, which leads to the transport of plasma iron to ferritin, presumably involves its reducing effect, converting transferrin iron from the ferric to the ferrous state. 3 There is also evidence that ascorbic acid improves iron utilization, presumably as a further result of its reducing action, 2 and some evidence that it may have a direct effect upon erythropoiesis. Ascorbic acid is further alleged to enhance the conversion of ferrous to a more physiologically active form, folic acid, which would make it even more important in the treatment of anemia since it would aid in the utilization of dietary folic acid. 9

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 astgreying of more ionizable forms of iron, and does not interfere with proteolytic or digestive 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. 12 Folic acid has also been shown to reduce circulating homocysteine levels in the blood. 15,16 Folate as 5-methyltetrahydrofolate and B12 as methylcobalamin are involved in the remethylation reaction of homocysteine to methionine. 11,12 Elevated homocysteine plasma levels are associated with increased risk of preeclampsia, neural tube defects, myoccardial infarction and artherosclerosis. 19-23

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. 1,3

INDICATIONS

For the treatment of all anemias responsive to oral 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).

SIDE EFFECTS

Average capsule doses in sensitive individuals or excessive dose 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. 14

DOSEAGE AND ADMINISTRATION

Usual adult dose is 1 soft gelatin capsule daily.

HOW SUPPLIED

Capsules: NDC 0281-0262-53, Bottle of 100 NDC 0281-0262-56, Bottle of 500

CAUTION: Federal law prohibits dispensing without prescription.

BIBLIOGRAPHY


REFERENCES


Manufactured for: SAVAGE LABORATORIES® a division of Allana Inc. MELVILLE, NEW YORK 11747 by: R. P. Scherer Corporation, St. Petersburg, Florida 33702 ©1996 Savage Laboratories®
Raise calcitriol therapy to a higher level.
Drive down elevated PTH with enhanced Calcijex® therapy.
(Calcitriol Injection)

RAISING THE LEVEL OF CALCITRIOL THERAPY.
For optimal patient management, enhanced Calcijex therapy...

- Represents a major change in initial and titration dosing guidelines.
- Provides an opportunity to intervene more aggressively in mild to severe secondary hyperparathyroidism.
- Significantly reduces morbidity caused by undertreated renal osteodystrophy... a therapeutic approach that is truly enhanced.\(^1\)\(^3\)
- Broadens your dosing range, allowing you to provide treatment commensurate with PTH levels.
- Corresponds to the practice of nephrology thought leaders for patients with markedly elevated PTH.

### Dosing highlights

<table>
<thead>
<tr>
<th></th>
<th>Enhanced therapy</th>
<th>Previous guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial dose</td>
<td>1-2 mcg q dialysis</td>
<td>0.5 mcg q dialysis</td>
</tr>
<tr>
<td>Titration dose</td>
<td>0.5-1 mcg q 2-4 weeks</td>
<td>0.25-0.5 mcg q 2-4 weeks</td>
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</table>

Enhanced Calcijex\(^\circledR\) (Calcitriol Injection) therapy refers to changes in dosing guidelines to encourage therapy commensurate with PTH level. Calcijex has not changed, only the suggested dosing guidelines as reflected in the accompanying brief disclosure.

### A pattern of success.

Representative patient with severe hyperparathyroidism: Initial 2 mcg calcitriol dose, 3 x per week increased incrementally to 6 mcg, 3 x per week. PTH decreased dramatically.\(^1\)

Measures to control calcium intake, including a low-calcium dialysate and strict control of phosphorus levels, limited hypercalcemia.
CALCIJEX®
CALCIOTROL INJECTION
1 mcg and 2 mcg/mL

BRIEF SUMMARY
INDICATIONS AND USAGE
Calciex® (calcitriol injection) is indicated in the management of hypocalcemia 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
Calciex (calcitriol injection) should not be given to patients with hypercalcemia or evidence of vitamin D toxicity.

WARNINGS
Since calcitriol 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 OVERDOSAGE). Progressive hyperparathyroidism due to overdosage 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 susceptible anatomical regions may be useful in the early detection of this condition.

PRECAUTIONS
1. General
Excessive dosage of Calcijex® (calcitriol injection) induces hypercalcemia and in some instances hypercalciuria; 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 digitalis, 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 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).

Adynamic bone disease may develop if PTH levels are suppressed to normal levels. If biopsy is not being done (and clinical suspicion reasons, PTH levels may be used to indicate the rate of bone turnover. PTH levels fall below recommended target range (1.5 to 3 times the upper limit of normal), in patients treated with Calcijex, the calcitriol dose should be reduced or therapy discontinued. Discontinuation of calcitriol therapy may result in rebound effect, therefore, appropriate titration toward a maintenance dose is recommended.

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

5. Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Calcijex (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 teratogenic in rabbits when given in doses 4 and 15 times the dose recommended for human use.

All 13 fetuses in 3 litters at these doses showed external and skeletal abnormalities. However, none of the other 23 litters (156 fetuses) showed significant abnormalities compared with controls.

Teratogenesis studies in rats showed no evidence of teratogenic potential. There are no adequate and well-controlled studies in pregnant women. Calcijex 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 Calcijex in pediatric patients have not been established.

ADVERSE REACTIONS
Adverse effects of Calcijex® (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, phosphatemia, rhinitis, hyperventilation, hypercalcemia, increased BUN, albuminuria, hypercalcemia, elevated SGOT and SGPT, osteudystrophy, hypertension, cardiac arrhythmies and, rarely, overt psychosis.

Occasional mild pain on injection has been observed.

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

1. Treatment of Hypercalcemia and Hypercalciuria 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 Calcijex therapy, institution of a low calcium diet and withdrawal of calcium supplements. Serum calcium levels should be determined daily until normocalcemia ensues. Hypercalcemia usually resolves in two to seven days. When serum calcium levels have returned to within normal limits, Calcijex therapy may be reinstituted at a dose 0.5 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 Adverse Effects of Calcitriol Injection
The treatment of acute accidental overdosage of Calcijex should consist of general supportive measures. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion and assessment of electrolyte 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 overdosage. 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, the use of 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 also has been reported.

HOW SUPPLIED
Calcijex® (calcitriol injection) is supplied in 1 mL ampuls containing 1 mcg (List No. 1200) and 2 mcg (List 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.
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Southern California Permanente Medical Group announces the formation of the
NATIONAL RENAL CREDENTIALING CENTER
a non-profit service for promoting quality, cost-effective management of renal disease.

The NRCC is guided by a Scientific Advisory Board that includes leaders in all facets of the renal care field.

Through its comprehensive credentialing process, the NRCC promotes measurable improvements in patient outcomes.

National Renal Credentialing Center
393 Walnut Street
Pasadena, CA 91188
Phone: (626) 405-3277
In renal failure patients, renal specific vitamin replacement is essential. The Nephro-Vite® family of renal vitamins is formulated to meet the special micronutrient replacement needs of renal failure patients.

Nephro-Vite® provides complete B and C vitamin replacement therapy, with increased amounts of folic acid and B6. It also includes B1, B2, B12, biotin, pantothenic acid and niacin.
Patency... The STRETCH Advantage

The overall stretch graft survival at 2 and 3 years equals or exceeds the best results reported in the literature with regular PTFE grafts.

CUMULATIVE SURVIVAL OF 420 GORE-TEX® STRETCH VASCULAR GRAFTS, 1991-1995

<table>
<thead>
<tr>
<th>Measure</th>
<th>1 Year</th>
<th>2 Years</th>
<th>3 Years</th>
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<tr>
<td>Secondary Patency (Graft Survival)</td>
<td>89%</td>
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<tr>
<td>Primary Patency (Clot-free Survival)</td>
<td>76%</td>
<td>72%</td>
<td>71%</td>
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W. L. Gore & Associates. Inc., Flagstaff, Arizona 86001-3200 • 800-528-4762
GORE-TEX is a registered trademark of W. L. Gore & Associates
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

Schein Pharmaceutical, Inc.
100 Campus Drive, Florham Park, NJ 07932

Please see references and prescribing information including the boxed WARNING on following page.
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INFeD® and EPO for target HCT range of 30% to 36%\textsuperscript{5,6}
- Treatment is currently targeted to a hematocrit range of 30% to 36%\textsuperscript{5}

INFeD® for effective erythropoiesis
- Erythropoiesis can rapidly mobilize iron reserves and deplete even ample iron stores\textsuperscript{1}

INFeD® for rapid iron repletion
- IV iron should be considered for all patients with low iron stores requiring a rapid EPO response\textsuperscript{14}
- 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…”\textsuperscript{7}

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.”\textsuperscript{5}

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
**INFeD (Iron Dextran Injections)**

**DESCRIPTION:** INFeD (iron dextran injection, USP) is a dark brown, slightly viscous sterile liquid complex of ferric hydroxide and dextran or intravenous or intramuscular injections.

Each mL of injection contains 50 mg of elemental iron (as iron dextran complex), approximately 0.5% sodium chloride, in water for injection. Sodium hydroxide and/or hydrochloric acid may have been used to adjust pH. The pH of the solution is between 5.2 and 6.4.

The iron dextran complex has an average molecular weight of 165,000.

**INDICATIONS:**

1. **Cardiovascular Disease:**
   - Management of chronic iron deficiency anemia in patients with cardiovascular disease (including those with coronary artery disease).
   - Management of iron deficiency anemia in patients with congestive heart failure.

2. **Hemoglobin Restoration:**
   - Restoration of hemoglobin levels in patients with iron deficiency anemia.

**CONTRAINDICATIONS:**

1. Patients with a history of hypersensitivity to iron, parenteral iron, or an iron dextran complex.
2. Patients with uncorrected hemolytic anemia.
3. Patients with uncorrected hemostatic defects.
4. Patients with a history of a known anaphylactic reaction to iron dextran.

**PRECAUTIONS:**

1. **Allergic Reactions:** Patients with a history of anaphylactic reactions to iron dextran or previous reactions to iron should not be treated with INFeD.
2. **Hematologic Factors:** Patients with uncorrected anemia, hemostatic defects, or uncorrected hemolytic anemia should not be treated with INFeD.
3. **Renal Function:** Patients with impaired renal function should be treated with INFeD with caution, and the dose should be reduced accordingly.

**DOSE AND ADMINISTRATION:**

1. **Dosage:** The dosage of INFeD should be determined by the patient's need for iron and the response to therapy. The dosage should be individualized to each patient.
2. **Route:** The usual route of administration is intramuscular injection. In rare instances, intravenous injection may be necessary.
3. **Dosage:** The recommended dosage of INFeD is 50 mg of elemental iron per kg of body weight per injection. The total amount of iron should be calculated based on the patient's need for iron and the patient's iron stores.

**REFERENCES:**

INSTRUCTIONS TO AUTHORS

Send manuscripts to the Editor:

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J. Am. Soc. Nephrol.
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Gainesville, Florida 32610

The Journal of the American Society of Nephrology will publish original manuscripts judged by peers to be of high quality and relevant to the broad field of nephrology. Nephrology is an alliance of scientists and physicians who seek to understand the functions of the kidneys and the means to improve the medical care of individuals with kidney disease. The strength and vitality of the discipline radiate, historically, from the dynamic interaction between the basic and the clinical sciences. The Journal strives to nurture this relationship by providing the means for communicating to nephrologists and others in related specialties critical information of broad significance in the field. Subjects appropriate for the Journal include, but are not restricted to:

- clinical nephrology
- cell and transport physiology
- pathology and immunology
- cell and structural biology
- pathophysiology of renal disease
- hormones, autacoids and growth factors
- hemodynamics, hypertension and vascular regulation
- dialysis
- transplantation
- mineral metabolism and bone disease
- molecular medicine, genetics, and development

General Information

Original manuscripts are of two types: Regular Articles and Brief Communications. Regular Articles are traditional full length papers that address research questions with exhaustive experimental design and methodology. Brief Communications should contain not more than 2000 words (including abstract, figures, tables and references) describing important new observations in nephrology. Reviews of basic and clinical topics of interest to the readership will be solicited by the editors.

In the cover letter, designate one author as the correspondent. The cover letter should include a statement explaining why the research is especially important. The journal office may solicit editorials to accompany articles that are especially newsworthy or controversial.

Include in the cover letter the names, addresses, telephone and fax numbers and areas of expertise of at least five individuals (peers) who may serve at the discretion of the editors, as reviewers of the manuscript.

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Include one of the two following statements on copyright interests signed by all authors: "In consideration of the American Society of Nephrology's taking action in reviewing and editing this submission, the author(s) undersigned hereby transfer(s), assign(s) or otherwise convey(s) all copyright ownership to the ASN in the event this work is published by the ASN."

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The signatures that must accompany the cover letter indicate that each author approved the final version of the manuscript and is prepared to take public responsibility for the work.

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It is the policy of the Journal to expedite manuscript review. Authors will receive within 7 days of receipt at the editorial office, acknowledgment that their manuscript has been forwarded to an associate editor and appropriate reviewers. Manuscripts that are judged by a panel of screening editors to fall outside the range of interest of the readership or that fail to satisfy technical requirements will be promptly returned to the authors without further review. In order to reduce postage expense, manuscripts sent to outside reviewers as privileged communications will be destroyed and not returned to the authors. Glossy prints and photographs from rejected manuscripts will be returned to authors.

Manuscript Preparation

- Submit an original manuscript and three photocopies, typed double-spaced in letter-quality print on one side only of standard (8½ x 11 inch) white bond paper. Manuscripts should be organized as follows: title page, abstract, introduction, methods, results, discussion, acknowledgments, references, tables and figure legends.
- On the title page type the full names, highest academic degrees and affiliations of all authors. The title should not exceed 100 characters including spaces between words. Number all pages consecutively beginning with the title page. Include an abbreviated title of not more than 40 characters.
- Abstract: State the problem considered, methods, results and conclusions in less than 250 words.
- Use of Systeme International d'Unites (SI) for measurements is preferred throughout the manuscript. Factors for converting frequently used components can be found in JAMA (1989; 262:200–202).
- Use generic names of drugs.
- Do not use abbreviations in the title. Define unusual abbreviations with the first use in the body of the manuscript. A list of accepted abbreviations can be found in the July and January issues of the Journal.
- Text footnotes should be typed on a separate page.
• Foreign contributors, whose language is not English, should obtain help from colleagues who are proficient in scientific English.

• 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.

• Tables: Type double-spaced on separate sheets of standard-sized white bone paper. Each table should have a title and be numbered in the order of appearance in the text. Use superscript letters to indicate footnotes typed at the bottom of the table.

• Figures: Four complete sets of glossy photographs of all figures including graphs, black and white light and electron micrographs and color photographs, must be submitted. The use of color illustrations is encouraged, but authors should contact the editor prior to their preparation for advice and assistance. All figures should be clearly labeled on the back. Photomicrographs should be sized to fit one column (8 cm) or two columns (17 cm); the maximum plate size is $17 \times 22$ cm.

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

Graphs must be of professional quality. Computer-generated graphs should be of laser quality.

High contrast prints for roentgenographic photographs and electron micrographs are essential.

Clear photocopies of the figures should be included with the original and each copy of the manuscript.

• References: References should be typed on a separate page and numbered in the order of appearance in the text, with only one reference to a number. Citation of unpublished observations or personal communications (include separately permission to quote from appropriate individual) should be placed in the text in parenthesis.

Journal articles, abstracts and books: List all authors for each article cited. Journal names should be abbreviated according to the BIOSIS list of serials.


• Manuscripts on Electronic Diskettes: Authors must submit electronic diskettes of the final version of their manuscripts along with the printout of the revised manuscript.

Diskettes produced on IBM or IBM-compatible computers are preferred, but those produced on most Macintosh computers can also be converted. Word and WordPerfect are preferred. Authors preparing diskettes on Macintosh computers should not use the Fast Save option. Files in ASCII are not preferred. Identify the diskette by providing journal name, manuscript number, senior author’s name, manuscript title, name of computer file, type of hardware, operating system and version number, and software program and version number. The journal does not assume responsibility for errors in conversion of customized software, newly released software, and special characters. Mathematics and tabular material will be processed in the traditional manner.

Manuscript Checklist
1. Include the original typed manuscript and three photocopies.
2. Send four sets of glossy print figures; each manuscript set should also contain photocopies of figures.
3. Include a cover letter containing a copyright transfer statement.
4. Include all authors’ personal signatures.
5. Designate a corresponding author and provide a telephone number, fax number and address.

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Please read, correct, and return the original set of proofs with the manuscript and figure copy. Be sure that all Editor’s or printer’s queries are answered. Only minor corrections are permitted.

Authors will be charged for excessive changes. Excess pages charges will be assessed on articles and brief communications that exceed four pages in length ($60.00 per printed page). Invited reviews and editorials will be exempt. The enclosed prints of your illustrations should be reviewed carefully and any corrections noted on the figure proof. Return the corrected proof and manuscript within 48 hours to: Journal Editing, Williams & Wilkins, 351 West Camden Street, Baltimore, MD 21201-2436.

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This bacterium can cost a life.¹,⁵

This Blue catheter can save it.⁴

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%,³ 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.

ARROWgard Blue®, the only antiseptic-impregnated CVC, has been shown to reduce the incidence of catheter-related bloodstream infection (CRBSI) by as much as 80%.⁴,⁵

Don’t take unnecessary chances. For more information, contact your Arrow representative or call us directly by dialing 800 523-8446 or 610 378-0131.

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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>
<th>Pre-study</th>
<th>Week 1</th>
<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>
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</table>

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.
INDICATIONS: Dexferum is indicated for treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible.

CONTRAINDICATIONS: Hypersensitivity to the product. All anemias not associated with iron deficiency.

WARNINGS: See BOXED WARNING.

The parenteral use of complexes of iron and carbohydrate has resulted in anaphylactic reactions. Deaths associated with such administration have been reported. Dexferum 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: Dexferum (Iron Dextran Injection, USP) is a dark brown, slightly viscous, sterile liquid complex of ferric hydroxide and a low molecular weight dextran derivative for intravenous use. Each mL contains 35 mg elemental iron as an iron dextran complex. Sodium citrate and citric acid may be added for isotony. Water for injection q.s. pH adjusted to 5.2-6.5 with hydrochloric acid and, if necessary, sodium hydroxide. Sterile, nonpyrogenic.

Therapeutic Class: Hematonic.

I N D I C A T I O N S: Dexferum is indicated for treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible.

CONTRAINDICATIONS: Hypersensitivity to the product. All anemias not associated with iron deficiency.

WARNINGS: See BOXED WARNING.

A risk of anaphylactoid reactions may exist in the intravenous injection of iron-carbohydrate complexes. Such complexes have been found under experimental conditions to produce anaphylactic reactions in certain individuals. Dexferum should be used with caution in patients with a history of such reactions as well as in those who have had previous reactions to the product. The incidence of possible anaphylactoid reactions may be increased by rapid intravenous injection or by the use of solutions other than sterile water for injection. Dexferum should be administered as a slow intravenous injection over a period of 5-15 minutes.

PRECAUTIONS: Dexferum should be given only in patients with previously demonstrated iron deficiency anemia.

The following adverse effects have been reported with the use of Dexferum: Hypersensitivity reactions have been reported in patients with previous reactions to the product. Hypersensitivity reactions, including anaphylactic reactions, have been reported with the use of Dexferum. Dexferum should be used with caution in patients with a history of such reactions as well as in those who have had previous reactions to the product. The incidence of possible anaphylactoid reactions may be increased by rapid intravenous injection or by the use of solutions other than sterile water for injection. Dexferum should be administered as a slow intravenous injection over a period of 5-15 minutes.

ADVERSE REACTIONS: General: Unusual infections with colonization of patients with pre-existing disease have been reported. Dexferum should be administered as a slow intravenous injection over a period of 5-15 minutes.

Contraindications: Hypersensitivity to the product. All anemias not associated with iron deficiency.

WARNINGS: See BOXED WARNING.

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Amgen congratulates and commends the leadership and members of the National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF-DOQI) for their dedication to improving outcomes for people with end-stage renal disease (ESRD). It is through their hard work and tireless efforts that the unprecedented DOQI practice guidelines have been developed and published.

Amgen has been a strong advocate and supporter of the DOQI since the initiative’s conception. We will continue our commitment to support programs that focus on high quality care, improved quality of life, reduced patient morbidity, and, most importantly, the chance for ESRD patients to live longer.

As the DOQI practice guidelines enter the implementation phase, we encourage the renal community to review them, consider their implications for patient outcomes and adopt those that are appropriate on a patient-to-patient basis. We also encourage the development of new clinical information and the ongoing examination of data to refine these guidelines so that the work remains current and supports the best outcomes for patients. These guidelines were developed to help identify optimal clinical practices which can have a profound effect on the lives of hundreds of thousands of ESRD patients.

Again, we at Amgen sincerely appreciate the integrity and dedication of the NKF-DOQI team.

Gordon Binder
Chairman and Chief Executive Officer
Amgen
**BC/BE Nephrologist**

To join a 6 physician group in their growing 100% Nephrology practice. Southern city of 250K. All aspects of Nephrology. Busy work days but home at a reasonable hour. Full benefits, generous time off. Excellent Salary leading to partnership. Reply to: JASN Box #1-9, 351 W. Camden Street-5N, Baltimore, MD 21201-2436.

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**Venous and Hemodialysis Access Symposium**

February 3-8, 1997
Keystone Resort ★ Keystone, Colorado
Sponsored by Indiana University School of Medicine’s Division of Continuing Medical Education and Department of Radiology
Course Director: Scott O. Trerotola, M.D.

This course is designed for interventional radiologists, nephrologists, vascular surgeons and other health care professionals engaged in the comprehensive care of patients with venous and hemodialysis access.

Experts from different disciplines will review and discuss current knowledge of the following topics: overview of hemodialysis access (including physical examination and catheter access), PTA of failing hemodialysis access, European perspective on hemodialysis access interventions, surgical revision of thrombosed hemodialysis access, cost and outcome analysis for hemodialysis access salvage, oncologist’s perspective on central venous access, alternative access for infusions and hemodialysis catheters, management of infected access sites, cost and outcomes in central venous access, venous thrombosis, management and temporary inferior vena cava filters, and transjugular intrahepatic portosystemic shunts.

For further information, call the Indiana University School of Medicine Division of Continuing Medical Education at (317) 274-8353.

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**Montana**

Large multispecialty group, N. Rockies University town, serving referral base of 250,000, seeks 2nd BC/BE nephrologist to replace retiring physician. Join 18 member IM department with all subspecialties represented. Practice covers 2 dialysis units, CAVH, CAPD, transplant follow-up. Unparalleled recreational opportunities in liveable small city with excellent schools. Excellent benefit package, competitive guarantee. Opportunity to teach students/residents from U of WA Med School.

Reply: D. Ramsey, Administrator, Western Montana Clinic, PO Box 7609, Missoula, MT 59807.

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**Scott & White**

Scott & White Clinic/Texas A&M University Health Science Center College of Medicine is seeking candidates for the position of Director of the Division of Nephrology. Excellent clinical skills, leadership ability, and a commitment to teaching are essential. Special interest in clinical research would be an asset. Salary and academic appointment are commensurate with qualifications. Scott & White is among the nation's largest integrated health care organizations. Temple is a city of 50,000 in Central Texas; trees and lakes are abundant, the climate is conducive to outdoor activities and recreational activities are plentiful. Austin, the capital of Texas and home of the University of Texas is 65 miles to the south while Baylor University is 35 miles to the north. Reply with CV and names of three references to:

Mike Nichols
Director of Physician Recruitment
Scott & White Clinic
2401 South 31st Street
Temple, TX 76508

Scott & White is an equal opportunity employer. For more information about Scott & White, please visit our internet site at: http://www.sw.org
# Application for Active and Corresponding Membership

**LAST NAME**

**FIRST NAME**

**MIDDLE INITIAL(S)**

**PREFERRED MAILING ADDRESS**

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<th>CITY</th>
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**BUSINESS ADDRESS (IF NOT LISTED ABOVE)**

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**BUSINESS TELEPHONE**

**BUSINESS FAX**

**E-MAIL ADDRESS**

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

*(Individuals residing in the U.S. with temporary visa status will apply for corresponding membership.)*

**Academic Appointment:**

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<th>Full Time</th>
<th>Part Time</th>
<th>None</th>
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**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)*

**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.)*

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<tr>
<th>Institutional Name/Address</th>
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Training in Nephrology *(Give *inclusive* dates for residences, fellowships, other relevant postgraduate education.)*

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

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

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List other societies to which you belong.

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

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

- **$125**—**ACTIVE MEMBERSHIP** for *residents* of North or Central America.
- **$140**—**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.

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

- [ ] Visa
- [ ] MasterCard

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CARDHOLDER’S NAME (PLEASE PRINT OR TYPE)  SIGNATURE

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CARD NUMBER  EXPIRATION DATE