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General: Nutropin AD should be prescribed by physicians experienced in the diagnosis and management of patients with growth failure due to GHD, Turner syndrome or chronic renal insufficiency. No studies have been completed of Nutropin AD therapy in patients who have received renal transplants. Currently, treatment of patients with functioning renal allografts is not indicated.

Because Nutropin AD may reduce insulin sensitivity, patients should be monitored for evidence of glucose intolerance.

Patients with a history of an intracranial lesion should be examined frequently for progression or recurrence of the lesion.

Patients with growth failure secondary to chronic renal insufficiency should be examined periodically for evidence of progression of renal osteodystrophy. Slipped capital femoral epiphysis or avascular necrosis of the femoral head may be seen in children with advanced renal osteodystrophy, and it is uncertain whether these problems are affected by growth hormone therapy. X-rays of the hips should be obtained prior to initiating therapy for CRI patients. Physicians and parents should be alert to the development of a limp or complaints of hip or knee pain in patients treated with Nutropin AD.

Slipped capital femoral epiphysis may also occur more frequently in patients with endocrine disorders or in patients undergoing rapid growth.

Progression of scoliosis can occur in patients who experience rapid growth. Because growth hormone increases growth rate, patients with a history of scoliosis who are treated with growth hormone should be monitored for progression of scoliosis.

Growth hormone has not been shown to increase the incidence of scoliosis. Skeletal abnormalities including scoliosis are commonly seen in untreated Turner syndrome patients. Physicians should be alert to these abnormalities, which may manifest during growth hormone therapy.

Patients with Turner syndrome should be evaluated carefully for otitis media and other ear disorders since these patients have increased compliance. In a randomized controlled trial, there was a statistically significant increase, as compared to untreated controls, in otitis media (48% vs. 29%) and ear disorders (118% vs. 5%) in patients receiving growth hormone. In addition, patients with Turner syndrome should be monitored closely for cardiovascular disorders (e.g., stroke, aortic aneurysm, hypertension) as these patients are also at risk for these conditions.

Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea and/or vomiting has been reported in a small number of patients treated with growth hormone products. Symptoms usually occurred within the first eight (8) weeks of use and resolved in those patients who discontinued therapy. Neurological consultation should be considered for patients with headaches and/or visual changes who are not otherwise treated.

Drug interaction: The use of Nutropin AD® (somatropin [hGH origin] injection) in patients with CRI receiving glucocorticosteroid therapy has not been evaluated. Concomitant glucocorticosteroid therapy may inhibit the growth-stimulating effect of Nutropin AD. If glucocorticosteroid replacement is required, the glucocorticosteroid dose should be carefully adjusted.

There was no evidence in the controlled studies of somatropin's interaction with drugs commonly used in CRI patients. Limited published data indicate that growth hormone treatment increases cytochrome P450 (CYP450) mediated anticoagulation in cats. These studies are not conclusive. In a clinical trial, sodium valproate increased the clearance of compounds known to be metabolized by CYP450 liver enzymes (e.g., corticosteroids, sex steroids, anticonvulsants, cyclosporine). Careful monitoring is advisable when a concomitant administration with other drugs known to be metabolized by CYP450 liver enzymes.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenesis, mutagenicity and reproduction studies have not been conducted with Nutropin AD.

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

Nursing Mothers: It is not known whether Nutropin AD is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nutropin AD is administered to a nursing mother.

Information for Patients: Patients being treated with growth hormone and/or their parents should be informed of the potential benefits and risks associated with treatment. If home use is desired, it is desirable to be familiar with the device and instructions on its use. The home use device should be kept on hand at all times.

ADVERSE REACTIONS
As with all protein pharmacueticals, a small percentage of patients may develop antibodies to the protein. Growth hormone antibody binding capacity less than 2 mg/L have not been associated with growth attenuation. In some cases when binding capacity exceeds 2 mg/L, growth attenuation has been observed. In clinical studies of patients that were treated with Nutropin AD® (somatropin [hGH origin] injection) for the first time, 9/107 growth hormone deficient (GHD) patients, 9/275 CRI patients and 0/12 Turner syndrome patients developed antibodies to growth hormone. Antibodies were found in 6/107 GHD patients, 16/275 CRI patients and 6/12 Turner syndrome patients. This represented 5.6%, 5.8% and 50% of patients that were treated with Nutropin AD® (somatropin [hGH origin] injection) for the first time, and 15%, 11% and 50% of patients that were treated with Nutropin AD® (somatropin [hGH origin] injection) for greater than one year. In both groups of patients, in the clinical studies, the antibody titers were all less than 20 U/L.

Injection site discomfort has been reported. This is more commonly observed in children switched from another growth hormone product to Nutropin AD.

Leukemia has been reported in a small number of growth hormone deficient patients treated with growth hormone. It is uncertain whether the increased risk is related to the pathogenesis of growth hormone deficiency itself, growth hormone therapy, or other associated treatments such as radiation therapy for intracranial tumors. On the basis of current evidence, experts cannot conclude that growth hormone therapy is responsible for these occurrences. The risk in GHD, CRI, or Turner syndrome patients, if any, remains to be established.

Other adverse drug reactions that have been reported in growth hormone-treated patients include the following:

1. Metabolic: Infrequent, mild and transient peripheral edema. 2. Musculoskeletal: Arthralgias, rare carpal tunnel syndrome. 3. Skin: Rare increased growth of pre-existing new, patients should be monitored carefully for malignancy transformation.

OVERDOSAGE
The recommended dosage for growth hormone deficiency is 0.3-0.35 mg/kg (approximately 0.90-1.05 U/kg) of body weight weekly. The recommended dosage for chronic renal insufficiency is up to 0.35 mg/kg (approximately 1.50 U/kg) of body weight weekly. The recommended dosage for Turner syndrome is up to 0.375 mg/kg (approximately 1.125 U/kg) of body weight weekly. Long-term overdosage could result in signs and symptoms of gigantism and/or acromegaly consistent with the known effects of excess human growth hormone.

DOSEAGE AND ADMINISTRATION
The Nutropin AD® (somatropin [hGH origin] injection) dosage and administration schedule should be individualized for each patient. Therapy should not be continued if nephrogenic tissue fusion has occurred. Response to growth hormone therapy tends to decrease with time. However, failure to increase growth rate, particularly during the first year of therapy, suggests the need for closer assessment of compliance and evaluation of other causes of growth failure, such as hypothyroidism, under-nutrition, and advanced bone age.

Dosage
Growth Hormone Deficiency (GHD)
A weekly dosage of up to 0.30 mg/kg (approximately 0.90 U/kg) of body weight divided into daily subcutaneous injections is recommended.

Chronic Renal Insufficiency (CRI)
A weekly dosage of up to 0.35 mg/kg (approximately 1.05 U/kg) of body weight divided into daily subcutaneous injections is recommended.

Nutropin AD therapy may be continued up to the time of renal transplantation.

In order to optimize therapy for patients who require dialysis, the following guidelines for injection schedule are recommended:

1. Hemodialysis patients should receive their injection at night just prior to going to sleep or at least 3-4 hours after their hemodialysis to prevent hematoma formation due to the heparin.

2. Chronic Cycling Peritoneal Dialysis (CCPD) patients should receive their injection in the morning after they have completed dialysis.

3. Chronic Ambulatory Peritoneal Dialysis (CAPD) patients should receive their injection in the evening at the time of the overnight exchange.

Turner Syndrome
A weekly dosage of up to 0.375 mg/kg (approximately 1.125 U/kg) of body weight divided into equal doses 3 to 7 times per week by subcutaneous injection is recommended.

Administration
A solution should be clear immediately after removal from the refrigerator. Occasionally, after refrigeration, you may notice that small colorless particles of protein are present in the solution. This is not unusual for solutions containing proteins. Avoid the vial to come in room temperature and gently swirl. If the solution is cloudy, the contents MIGHT NOT be injected.

Before needle insertion, wipe the injection site of the Nutropin AD® (somatropin [hGH origin] injection) vial with rubbing alcohol or an antiseptic solution to prevent contamination of the contents by microorganisms that may be introduced by repeated needle insertions. It is recommended that Nutropin AD be administered using sterile, disposable syringes and needles. The syringes should be of small enough volume that the prescribed dose can be drawn from the vial with reasonable accuracy.

STABILITY AND STORAGE
Vial contents are stable for 28 days after initial use when stored at 2-8°C/36-46°F (under refrigeration). Avoid freezing the vial of Nutropin AD.

HOW SUPPLIED
Nutropin AD is supplied as 10 mg (approximately 30 ml of sterile liquid somatropin per vial.

Each carton contains six small vial cartons containing one 2 ml vial of Nutropin AD® (somatropin [hGH origin] injection) (5 mg/ml). NDC 505242-114-11

Nutropin AD® (somatropin [hGH origin] injection) manufactured by:

Genentech, Inc.
460 portrait San Bruno Boulevard
South San Francisco, CA 94080-4950

©1997 Genentech, Inc. Revised March, 1997
Nutropin AD® (somatropin [DNA origin] injection) is a human growth hormone (GH) produced by recombinant DNA technology. Recombinant DNA technology is used to instruct a yeast cell to produce GH. The yeast cell is engineered so that the product is identical to that of pituitary-derived human growth hormone. The protein is synthesized by a specific laboratory strain of yeast as a precursor consisting of the GH molecule preceded by the signal sequence from an eukaryotic protein. This precursor is cleaved in the endoplasmic reticulum and the native protein is secreted into the periplasm so that the protein is folded appropriately as it is synthesized.

Nutropin AD® is a highly purified preparation. Biological potency is determined by measuring the increase in body weight induced in hypophysectomized adult rats. Radiolabeled GH radioimmunoassay (RIA) is used to determine the purity and homogeneity of the preparation. The desensitized form of growth hormone has been extensively characterized and has been shown to be safe and fully active.

Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

Actions that have been demonstrated for Nutropin AD®, somatropin, somatotropin and/or pituitary-derived human growth hormone include:

- **Stature Growth**
  - Nutropin AD® stimulates skeletal growth in patients with growth failure due to a lack of adequate secretion of endogenous growth hormone or secondary to chronic renal insufficiency and in patients with Turner syndrome. Skeletal growth is accomplished at the epiphyseal plates of the ends of a growing bone. Growth and histological studies of the skeletal plates in children, adolescents and adults have shown that the consistency and shape of the plates, known as ‘growth plate’ is normal. Levels of insulin-like growth factor-I are low in children and adolescents who are growth hormone insufficients, but increase during treatment with Nutropin AD®. The response at the epiphyseal plates is consistent with the achievement of normal height adults. Results in the older children and adolescents who are GH-deficient may be limited due to a reduction in the growth plate and reduced height velocity.

- **Bone Turnover**
  - Bone turnover has been assessed in two studies. In the first study, trabecular bone formation rate (BFR) was determined in patients with Turner syndrome. Eight patients who received Nutropin AD® resulted in a significant increase of BFR as compared to placebo. In the second study, four patients with Turner syndrome were treated with Nutropin AD® and the rate of bone turnover was determined. In the third study, four patients with Turner syndrome were treated with Nutropin AD® and the rate of bone turnover was determined.

- **Glycemic Control**
  - Nutropin AD® stimulates glucose uptake in the liver and in the peripheral tissues. This results in a decrease in plasma glucose levels. The effect of Nutropin AD® on glycemic control is consistent with the known physiological effect of GH on glucose metabolism.

- **Cardiovascular System**
  - GH has a vasoconstrictor effect on the cardiovascular system. This effect is most pronounced in patients with Turner syndrome. The increase in blood pressure is consistent with the increase in systemic vascular resistance.

- **Muscle Mass**
  - GH stimulates muscle mass in patients with Turner syndrome. The increase in muscle mass is consistent with the increase in the rate of protein synthesis and the decrease in the rate of protein breakdown.

- **Adiposity**
  - GH has an anabolic effect on body composition. This effect is consistent with the increase in muscle mass and the decrease in body fat.

- **Morphometric Changes**
  - Nutropin AD® results in a decrease in plasma renin activity (PRA) in patients with Turner syndrome. The decrease in PRA is consistent with the decrease in systemic vascular resistance.

- **Hematologic Changes**
  - Nutropin AD® results in an increase in hematocrit in patients with Turner syndrome. The increase in hematocrit is consistent with the increase in red blood cell mass.

- **Metabolic Changes**
  - Nutropin AD® results in a decrease in serum triglycerides and an increase in HDL cholesterol in patients with Turner syndrome. The decrease in triglycerides and the increase in HDL cholesterol are consistent with the decrease in systemic vascular resistance.

- **Gastrointestinal Changes**
  - Nutropin AD® results in an increase in appetite and an increase in body weight in patients with Turner syndrome. The increase in appetite and body weight is consistent with the increase in food intake and the increase in body weight.

- **Other Changes**
  - Nutropin AD® results in an increase in the rate of bone turnover in patients with Turner syndrome. The increase in bone turnover is consistent with the increase in bone formation.

- **Clinical Pharmacology**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Pituitary-Derived Growth Hormone**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Actions**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Terminology**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Indications and Usage**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Adverse Reactions**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Contraindications**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Warnings**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Precautions**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **NCH**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Pharmacokinetics**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Pharmacodynamics**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Interactions**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Overdosage**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Dosage and Administration**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **Clinical Studies**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.

- **References**
  - Nutropin AD® is a sterile liquid intended for subcutaneous administration. The product is nearly isotonic at a concentration of 5 mg of growth hormone per mL and has a pH of approximately 5.0.
Reduce the Pressure of Hypertension

- Effective as monotherapy¹
- Effective in combination with other antihypertensive agents¹²

Well Tolerated

- Like other alpha₁-blockers, HYTRIN can cause marked lowering of blood pressure, especially postural hypotension and syncope.¹
- Caution should be observed when HYTRIN is administered concomitantly with other antihypertensive agents, especially the calcium channel blocker verapamil, to avoid the possibility of developing significant hypotension. Dosage reduction and retitration of either agent may be necessary.¹
- Adverse events occurring significantly more often than placebo in hypertension clinical trials were dizziness, asthenia, nasal congestion, peripheral edema, somnolence, nausea, palpitations and blurred vision.¹

HYTRIN FREE START™ PROGRAM

Free patient samples available. Call: 1-800-ABBOTT-5 ext. 250 for more information.

References:
1. HYTRIN package insert, Abbott Laboratories.

Abbott Laboratories
North Chicago, Illinois 60064
©1997, Abbott Laboratories Inc.

HYTRIN TERAZOSIN HCI CAPSULES

Reduce the Pressure

Please see the following page for brief summary of prescribing information.
HYTRIN® (terazosin hydrochloride) Capsules

INDICATIONS AND USAGE: HYTRIN is indicated for the treatment of hypertension in patients, including those with left ventricular hypertrophy, who are not responsive to diuretics and other antihypertensive agents such as diuretics or beta-adrenergic blocking agents alone. Patients with left ventricular hypertrophy have been treated with HYTRIN capsules in a placebo-controlled study. These patients were predominantly male, and the majority had hypertension. In this study, HYTRIN capsules were shown to be effective in reducing blood pressure in patients with left ventricular hypertrophy.

In routine clinical practice, HYTRIN capsules are contraindicated in patients known to be hypersensitive to terazosin hydrochloride. WARNINGS: Syncpe and "First-dose" Effect: HYTRIN capsules may cause dizziness upon the first dose or first few days of therapy. Patients should be warned if therapy is initiated for several days and then "first-dose" effect can be anticipated if therapy is reinitiated after a period of discontinuation. In a study of hypertensive patients, the incidence of syncpe occurring with the first dose of HYTRIN capsules was about 1%.

PRECAUTIONS: General: Use of HYTRIN in patients with left ventricular hypertrophy should be approached with caution, and patients should be warned of the potential for postural hypotension and should be monitored closely during initiation of therapy.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Terazosin, the active ingredient of HYTRIN, is a competitive, selective alpha-1-adrenergic blocking agent. The carcinogenic potential of terazosin has not been determined in standard two-year bioassays in rodents. However, terazosin and related triazolotriazines have been shown to be non-genotoxic in standard tests for mutagenicity. In a fertility study conducted in rats, terazosin treatment decreased the number of live pups per litter in a dose-related fashion. The no-effect dose was 0.1 mg/kg/day. The relevance of these findings to humans is unknown.

Drug Interactions: In controlled trials, terazosin has been added to diuretics, and several beta-adrenergic blockers: no unexpected or clinically significant interactions were detected. As with other alpha-adrenergic blocking agents, HYTRIN should be used with caution in patients with a history of hypersensitivity to beta-blocking agents.

ADVERSE REACTIONS: The most common adverse reactions were dizziness, palpitations, chest pain, chest discomfort, palpitations, and edema. Other adverse reactions reported in clinical trials, in order of frequency, include headache, hypotension, dizziness, chest pain, palpitations, chest discomfort, chest pressure, and edema.

In patients with left ventricular hypertrophy, the most common adverse reactions reported were dizziness, palpitations, chest pain, chest discomfort, chest pressure, and edema.

ADVERSE EVENT: Hypertension: The dose of HYTRIN and the dose interval (12 hours) should be adjusted based on the individual blood pressure response. The following is a guide to dosage:

Chemiluminescent: 1 mg at bedtime is the starting dose for all patients, and this dose should not be exceeded. This initial dosing regimen should be strictly observed to minimize the potential for adverse effects. Subsequent Doses: The dose may be slowly increased to a maximum of 20 mg of blood pressure response. The usual recommended dose is 1 mg at bedtime. However, some patients may benefit from doses as high as 40 mg. Increases above 40 mg may be given in increments of 20 mg. Further blood pressure effect and doses over 40 mg have not been studied. Blood pressure should be monitored at the end of the dosing interval, and also within the first 6 hours of the next interval. It may also be helpful to measure blood pressure at 0.5-hour intervals during the initial dosing regimen. It may also be helpful to measure blood pressure 3 or 4 hours after the last dose in patients with sleep apnea syndrome who have experienced positive responses and, to evaluate abnormalities of breathing or apnea which may result from excessive hypotensive response. In addition, a gradual increase in dose or use of a twice a day regimen can be considered. If terazosin (titration of the same dosage over a longer period of time) is being used to treat patients with hypertension, the patient should be advised to discontinue the treatment if the blood pressure response is not adequate. Use with Other Drugs: Caution should be observed when HYTRIN is administered concomitantly with other antihypertensive agents, especially diuretics, due to the possibility of developing significant hypotensive response. If HYTRIN is being used as an antianginal agent, the patient should be advised to discontinue the treatment if the blood pressure response is not adequate. Use with Other Drugs: Caution should be observed when HYTRIN is administered concomitantly with other antihypertensive agents, especially diuretics, due to the possibility of developing significant hypotensive response.
# Application for Active and Corresponding Membership

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<th>LAST NAME</th>
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**Preferred Mailing Address**

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**Business Address (if not listed above)**

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**Business Telephone**

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Date of Birth__________________ Sex__________________ Country of Citizenship__________________

*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>Part Time</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)*

**Please indicate the amount of time spent on the following. Your total should amount to 100%.*

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<th>Administration</th>
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**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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**For office use only:**

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

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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.

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

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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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