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### Friday, January 17, 1997

#### GENERAL SESSION I:

##### RESEARCH TO CLINICAL MANAGEMENT: INSIGHTS FOR DIABETES CARE

- APC97-01 **New Techniques in the Diagnosis of Vascular Disease,** *Richard W. Nesto, MD*  
8:00am - 8:40am
- APC97-03 **Immune Markers and the Risk for Type I Diabetes,** *George S. Eisenbarth, MD, PhD*  
9:20am - 10:00am
- APC97-04 **Insulin Action at the Cellular Level - Clinical Implications,** *Michael Mueckler*  
11:00am - 11:40am
- APC97-05 **Role of Oxidants and Antioxidant Therapy in Diabetic Complications,** *George L. King, MD*  
11:40am - 12:20pm

#### GENERAL SESSION II-A:

##### ENDOCRINOLOGY ISSUES

- APC97-06 **The Latest Treatment Options for Osteoporosis,** *Louis Avioli, MD*  
1:30pm - 2:10pm  
Availability Pending Speaker Release
- APC97-07 **Pharmacologic Treatment of Impotence,** *Fran E. Kaiser, MD*  
2:10pm - 2:50pm
- APC97-08 **Minerals and Hypertension,** *Lawrence M. Resnick, MD*  
3:35pm - 4:15pm  
Availability Pending Speaker Release
- APC97-09 **Endocrinology of Prostate Disease,** *Jean Wilson, MD*  
4:15pm - 4:55pm

#### GENERAL SESSION II-B:

##### DIABETES AND THE OLDER ADULT

- APC97-10 **Assessment of the Older Adult,** *Cecilia C. Boyer, RN, MS, CDE*  
1:30pm - 2:00pm
- APC97-11 **Treatment and Management of Diabetes in the Older Adult,** *Arshag D. Mooradian, MD*  
2:00pm - 2:50pm
- APC97-12 **Psycho-Social Aspects and Nutritional Management of Diabetes in the Older Adult,** *Sue McLaughlin, RD, CDE*  
3:35pm - 4:50pm
- APC97-13 **Special Issues - Case Studies,** *Cecilia C. Boyer, RN, MS, CDE, Sue McLaughlin, RD, CDE*  
4:05pm - 4:35pm

### Saturday, January 18

#### GENERAL SESSION III:

##### DIABETES IN THE FUTURE

- APC97-15 **Defining Quality Care in a Managed Care Organization,** *Neil Solomon, MD*  
8:00am - 8:40am
- APC97-16 **Ensuring Quality Diabetes Care-Review of the American Diabetes Association's Provider Recognition Program,** *David K. McCulloch, MD*  
8:40am - 9:20am
- APC97-17 **Defining Quality Care: A Purchaser's Perspective,** *Barbara Fleming, MD, PhD*  
9:20am - 10:00am
- APC97-18 **New Pharmacologic Treatment Options for Diabetes,** *Harold E. Lebovitz, MD*  
11:00am - 11:40am
- APC97-19 **Update on Implantable Pumps,** *Christopher D. Saudek, MD*  
11:40am - 12:20pm

### Sunday, January 19

#### GENERAL SESSION IV:

##### OBESITY - WHAT'S NEW IN TREATMENT AND MANAGEMENT?

- APC97-20 **Physiology of Body Weight Regulation,** *Xavier Pi-Sunyer, MD, MPH*  
8:00am - 8:35am
- APC97-21 **Effective Communication Strategies for Implementing Lifestyle Behavior Changes,** *William H. Polonsky, PhD, CDE*  
8:35am - 9:10am
- APC97-22 **The Non-Pharmacologic Treatments for the Obese Type II Patient,** *Marion Franz, MS, RD, CDE*  
9:10am - 9:45am
- APC97-23 **Pharmacologic Agents in the Treatment of Obesity,** *Richard W. Atkinson, MD*  
10:05am - 10:40am
- APC97-24 **Discussion, Morning Panel Sessions**  
10:40am - 11:30am

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any one  
antihypertensive.



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WAS ADDED TO HER REGIMEN.

Some people's hypertension is more difficult to control than others. That's why there's Cardura. Cardura delivers powerful antihypertensive efficacy comparable with the other major classes of agents when used as monotherapy. Cardura can also be used with ACE inhibitors, beta blockers, calcium channel blockers, or diuretics.<sup>1,2</sup> Cardura has no adverse effect on the lipid profile, blood glucose, or insulin levels.<sup>3,4</sup>

Also, Cardura is well tolerated. The side effects reported significantly more often than placebo in hypertension studies were dizziness, somnolence, and fatigue. These were generally mild and transient. Only 2% of patients discontinued therapy due to adverse effects—the same as with placebo. Syncope has been reported, but rarely (<1%). Therefore, as with all alpha blockers, careful titration and blood pressure monitoring is important.

So next time you're faced with a patient who is difficult to control, prescribe Cardura.

ONCE-A-DAY  
**CARDURA**®   
(doxazosin mesylate) Scored Tablets  
1 mg, 2 mg, 4 mg, 8 mg

*Please see brief summary of  
prescribing information on adjacent page.*

TAKES THE PRESSURE OFF

**References:** 1. Neaton JD, Grimm RH Jr, Prineas RJ, et al. for the Treatment of Mild Hypertension Study Research Group. Treatment of Mild Hypertension Study: final results. *JAMA*. 1993;270:713-724. 2. Soltero I, Guevára J, Silva H, Velasco M. A multicenter study of doxazosin in the treatment of severe essential hypertension. *Am Heart J*. 1988;116:1767-1771. 3. Ferrara LA, Di Marino L, Russo O, Marotta T, Mancini M, on behalf of the DoCHH Study Group. Doxazosin and captopril in mildly hypercholesterolemic hypertensive patients: the Doxazosin-Captopril in Hypercholesterolemic Hypertensives Study. *Hypertension*. 1993;21:97-104. 4. Lehtonen A, the Finnish Multicenter Study Group. Lowered levels of serum insulin, glucose, and cholesterol in hypertensive patients during treatment with doxazosin. *Current Therapeutic Research*. 1990;47:278-284.

**CARDURA® (doxazosin mesylate) Tablets**  
**Brief Summary of Prescribing Information**  
**INDICATIONS AND USAGE**

CARDURA (doxazosin mesylate) is indicated for the treatment of hypertension. CARDURA may be used alone or in combination with diuretics or beta-adrenergic blocking agents. There is limited experience with CARDURA in combination with angiotensin converting enzyme inhibitors or calcium channel blockers.

**CONTRAINDICATIONS**

CARDURA is contraindicated in patients with a known sensitivity to quinazolines (e.g. prazosin, terazosin).

**WARNINGS**

**Syncope and "First-dose" Effect:**

Doxazosin, like other alpha-adrenergic blocking agents, can cause marked hypotension, especially in the upright position, with syncope and other postural symptoms such as dizziness. Marked orthostatic effects are most common with the first dose but can also occur when there is a dosage increase, or if therapy is interrupted for more than a few days. To decrease the likelihood of excessive hypotension and syncope, it is essential that treatment be initiated with the 1 mg dose. The 2, 4, and 8 mg tablets are not for initial therapy. Dosage should then be adjusted slowly (see **DOSE AND ADMINISTRATION** section) with increases in dose every two weeks. Additional antihypertensive agents should be added with caution.

Patients being titrated with doxazosin should be cautioned to avoid situations where injury could result should syncope occur.

In an early investigational study of the safety and tolerance of increasing daily doses of doxazosin in normotensives beginning at 1 mg/day, only 2 of 6 subjects could tolerate more than 2 mg/day without experiencing symptomatic postural hypotension. In another study of 24 healthy normotensive male subjects receiving initial doses of 2 mg/day of doxazosin, seven (29%) of the subjects experienced symptomatic postural hypotension between 0.5 and 6 hours after the first dose necessitating termination of the study. In this study 2 of the normotensive subjects experienced syncope. Subsequent trials in hypertensive patients always began doxazosin dosing at 1 mg/day resulting in a 4% incidence of postural side effects at 1 mg/day with no cases of syncope.

In multiple dose clinical trials involving over 1500 patients with dose titration every one to two weeks, syncope was reported in 0.7% of patients. None of these events occurred at the starting dose of 1 mg and 1.2% (8/664) occurred at 16 mg/day.

If syncope occurs, the patient should be placed in a recumbent position and treated supportively as necessary.

**PRECAUTIONS**

**General**

**1. Orthostatic Hypotension:**

While syncope is the most severe orthostatic effect of CARDURA, other symptoms of lowered blood pressure, such as dizziness, lightheadedness, or vertigo, can occur, especially at initiation of therapy or at the time of dose increases. These were common in clinical trials, occurring in up to 23% of all patients treated and causing discontinuation of therapy in about 2%.

In placebo controlled titration trials orthostatic effects were minimized by beginning therapy at 1 mg per day and titrating every two weeks to 2, 4, or 8 mg per day. There was an increased frequency of orthostatic effects in patients given 8 mg or more, 10%, compared to 5% at 1-4 mg and 3% in the placebo group.

Patients in occupations in which orthostatic hypotension could be dangerous should be treated with particular caution.

If hypotension occurs, the patient should be placed in the supine position and, if this measure is inadequate, volume expansion with intravenous fluids or vasopressor therapy may be used. A transient hypotensive response is not a contraindication to further doses of CARDURA.

**2. Impaired Liver function:**

CARDURA should be administered with caution to patients with evidence of impaired hepatic function or to patients receiving drugs known to influence hepatic metabolism. There is no controlled clinical experience with CARDURA in patients with these conditions.

**3. Leukopenia/Neutropenia:**

Analysis of hematologic data from patients receiving CARDURA in controlled clinical trials showed that the mean WBC (N=474) and mean neutrophil counts (N=419) were decreased by 2.4% and 1.0% respectively, compared to placebo, a phenomenon seen with other alpha blocking drugs. A search through a data base of 2400 patients revealed 4 in which drug-related neutropenia could not be ruled out. Two had a single low value on the last day of treatment. Two had stable, non-progressive neutrophil counts in the 1000/mm<sup>3</sup> range over periods of 20 and 40 weeks. In cases where follow-up was available the WBCs and neutrophil counts returned to normal after discontinuation of CARDURA. No patients became symptomatic as a result of the low WBC or neutrophil counts.

**Information for Patients:**

Patients should be made aware of the possibility of syncope and orthostatic symptoms, especially at the initiation of therapy, and urged to avoid driving or hazardous tasks for 24 hours after the first dose, after a dosage increase, and after interruption of therapy when treatment is resumed. They should be cautioned to avoid situations where injury could result should syncope occur during initiation of doxazosin therapy. They should also be advised of the need to sit or lie down when symptoms of lowered blood pressure occur, although these symptoms are not always orthostatic, and to be careful when rising from a sitting or lying position. If dizziness, lightheadedness, or palpitations are bothersome they should be reported to the physician, so that dose adjustment can be considered. Patients should also be told that drowsiness or somnolence can occur with doxazosin, requiring caution in people who must drive or operate heavy machinery.

**Drug Interactions:**

Most (98%) of plasma doxazosin is protein bound. *In vitro* data in human plasma indicate that CARDURA has no effect on protein binding of digoxin, warfarin, phenytoin or indomethacin. There is no information on the effect of other highly plasma protein bound drugs on doxazosin binding. CARDURA has been administered without any evidence of an adverse drug interaction to patients receiving thiazide diuretics, beta blocking agents, and nonsteroidal anti-inflammatory drugs.

**Cimetidine:**

In a placebo-controlled trial in normal volunteers, the administration of a single 1 mg dose of doxazosin on day 1 of a four-day regimen of oral cimetidine (400 mg twice daily) resulted in a 10% increase in mean AUC of doxazosin ( $p=0.006$ ), and a slight but not statistically significant increase in mean  $C_{max}$  and mean half-life of doxazosin. The clinical significance of this increase in doxazosin AUC is unknown.

**Drug/Laboratory test interactions:**

None known.

**Cardiac Toxicity in Animals:**

An increased incidence of myocardial necrosis or fibrosis was displayed by Sprague-Dawley rats after 6 months of dietary administration at concentrations calculated to provide 80 mg doxazosin/kg/day and after 12 months of dietary administration at concentrations calculated to provide 40 mg doxazosin/kg/day (150 times the maximum recommended human dose assuming a patient weight of 60 kg). Myocardial fibrosis was observed in both rats and mice treated in the same manner with 40 mg doxazosin/kg/day for 18 months. No cardiotoxicity was observed at lower doses (up to 10 or 20 mg/kg/day, depending on the study) in either species. These lesions were not observed after 12 months of oral dosing in dogs and Wistar rats at maximum doses of 20 mg/kg/day and 100 mg/kg/day, respectively. There is no evidence that similar lesions occur in humans.

**Carcinogenesis, Mutagenesis and Impairment of Fertility:**

Chronic dietary administration (up to 24 months) of doxazosin mesylate at maximally tolerated concentrations (highest dose 40 mg/kg; about 150 times the maximum recommended human dose of 16 mg/60 kg) revealed no evidence of carcinogenicity in rats. There was also no evidence of

carcinogenicity in a similarly conducted study (up to 18 months of dietary administration) in mice. The mouse study, however, was compromised by the failure to use a maximally tolerated dose of doxazosin.

Mutagenicity studies revealed no drug- or metabolite-related effects at either chromosomal or subchromosomal levels.

Studies in rats showed reduced fertility in males treated with doxazosin at oral doses of 20 (but not 5 or 10) mg/kg/day, about 75 times the maximum recommended human dose. This effect was reversible within two weeks of drug withdrawal.

**Pregnancy**

**Teratogenic Effects, Pregnancy Category C.** Studies in pregnant rabbits and rats at daily oral doses of up to 41 and 20 mg/kg, respectively (154 and 75 times the maximum recommended daily dose of 16 mg, assuming a patient weight of 60 kg), have revealed no evidence of harm to the fetus. A dosage regimen of 82 mg/kg/day in the rabbit was associated with reduced fetal survival. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, CARDURA should be used during pregnancy only if clearly needed.

Radioactivity was found to cross the placenta following oral administration of labelled doxazosin to pregnant rats.

**Nonteratogenic Effects.** In peri-postnatal studies in rats, postnatal development at maternal doses of 40 or 50 mg/kg/day of doxazosin was delayed as evidenced by slower body weight gain and a slightly later appearance of anatomical features and reflexes.

**Nursing Mothers**

Studies in lactating rats given a single oral dose of 1 mg/kg of [<sup>14</sup>C]-doxazosin indicate that doxazosin accumulates in rat breast milk with a maximum concentration about 20 times greater than the maternal plasma concentration. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CARDURA is administered to a nursing mother.

**Pediatric Use**

Safety and effectiveness in children have not been established.

**ADVERSE REACTIONS**

CARDURA has been administered to approximately 4000 patients, of whom 1679 were included in the clinical development program. In that program, minor adverse effects were frequent, but led to discontinuation of treatment in only 7% of patients. In placebo-controlled studies adverse effects occurred in 49% and 40% of patients in the doxazosin and placebo groups, respectively, and led to discontinuation in 2% of patients in each group. The major reasons for discontinuation were postural effects (2%), edema, malaise/fatigue, and some heart rate disturbance, each about 0.7%.

In controlled clinical trials directly comparing CARDURA to placebo there was no significant difference in the incidence of side effects, except for dizziness (including postural), weight gain, somnolence and fatigue/malaise. Postural effects and edema appeared to be dose related.

The prevalence rates presented below are based on combined data from placebo-controlled studies involving once daily administration of doxazosin at doses ranging from 1-16 mg. The following summarizes those adverse experiences (possibly/probably related) reported for patients in these studies where the prevalence rate in the doxazosin group was at least 0.5% or where the reaction is of particular interest.

**Adverse reactions during placebo-controlled studies with doxazosin (n=339) and placebo (n=336), respectively:** Cardiovascular—Dizziness: 19% and 9%; Vertigo: 2% and 1%; Postural Hypotension: 0.3% and 0%; Edema: 4% and 3%; Palpitation: 2% and 3%; Arrhythmia: 1% and 0%; Hypotension: 1% and 0%; Tachycardia: 0.3% and 1%; Peripheral Ischemia: 0.3% and 0%; Skin Appendages—Rash: 1% and 1%; Pruritus: 1% and 1%; Musculoskeletal—Arthralgia/Arthritis: 1% and 0%; Muscle Weakness: 1% and 0%; Myalgia: 1% and 0%; Central & Peripheral N.S.—Headache: 14% and 16%; Paresthesia: 1% and 1%; Kinetic Disorders: 1% and 0%; Ataxia: 1% and 0%; Hypertonica: 1% and 0%; Muscle Cramps: 1% and 0%; Autonomic—Mouth Dry: 2% and 2%; Flushing: 1% and 0%; Special Senses—Vision Abnormal: 2% and 1%; Conjunctivitis/Eye Pain: 1% and 1%; Tinnitus: 1% and 0.3%; Psychiatric—Somnolence: 5% and 1%; Nervousness: 2% and 2%; Depression: 1% and 1%; Insomnia: 1% and 1%; Sexual Dysfunction: 2% and 1%; Gastrointestinal—Nausea: 3% and 4%; Diarrhea: 2% and 3%; Constipation: 1% and 1%; Dyspepsia: 1% and 1%; Flatulence: 1% and 1%; Abdominal Pain: 0% and 2%; Vomiting: 0% and 1%; Respiratory—Rhinitis: 3% and 1%; Dyspnea: 1% and 1%; Epistaxis: 1% and 0%; Urinary—Polyuria: 2% and 0%; Urinary Incontinence: 1% and 0%; Micturition Frequency: 0% and 2%; General—Fatigue/Malaise: 12% and 6%; Chest Pain: 2% and 2%; Asthenia: 1% and 1%; Face Edema: 1% and 0%; Pain: 2% and 2%.

Additional adverse reactions have been reported, but these are, in general, not distinguishable from symptoms that might have occurred in the absence of exposure to doxazosin. The following adverse reactions occurred with a frequency of between 0.5% and 1%: syncope, hypoesthesia, increased sweating, agitation, increased weight. The following additional adverse reactions were reported by <0.5% of 3960 patients who received doxazosin in controlled or open, short- or long-term clinical studies, including international studies. Cardiovascular System: angina pectoris, myocardial infarction, cerebrovascular accident; Autonomic Nervous System: pallor; Metabolic: thirst, gout, hypokalemia; Hematopoietic: lymphadenopathy, purpura; Reproductive System: breast pain; Skin Disorders: alopecia, dry skin, eczema; Central Nervous System: paresis, tremor, twitching, confusion, migraine, impaired concentration; Psychiatric: paranoia, amnesia, emotional lability, abnormal thinking, depersonalization; Special Senses: parosmia, earache, taste perversion, photophobia, abnormal lacrimation; Gastrointestinal System: increased appetite, anorexia, fecal incontinence, gastroenteritis; Respiratory System: bronchospasm, sinusitis, coughing, pharyngitis; Urinary System: renal calculus; General Body System: hot flushes, back pain, infection, fever/rigors, decreased weight, influenza-like symptoms.

CARDURA has not been associated with any clinically significant changes in routine biochemical tests. No clinically relevant adverse effects were noted on serum potassium, serum glucose, uric acid, blood urea nitrogen, creatinine or liver function tests. CARDURA has been associated with decreases in white blood cell counts (See Precautions).

**OVERDOSAGE**

No data are available in regard to overdosage in humans.

The oral LD<sub>50</sub> of doxazosin is greater than 1000 mg/kg in mice and rats. The most likely manifestation of overdosage would be hypotension, for which the usual treatment would be intravenous infusion of fluid. As doxazosin is highly protein bound, dialysis would not be indicated.

**DOSE AND ADMINISTRATION**

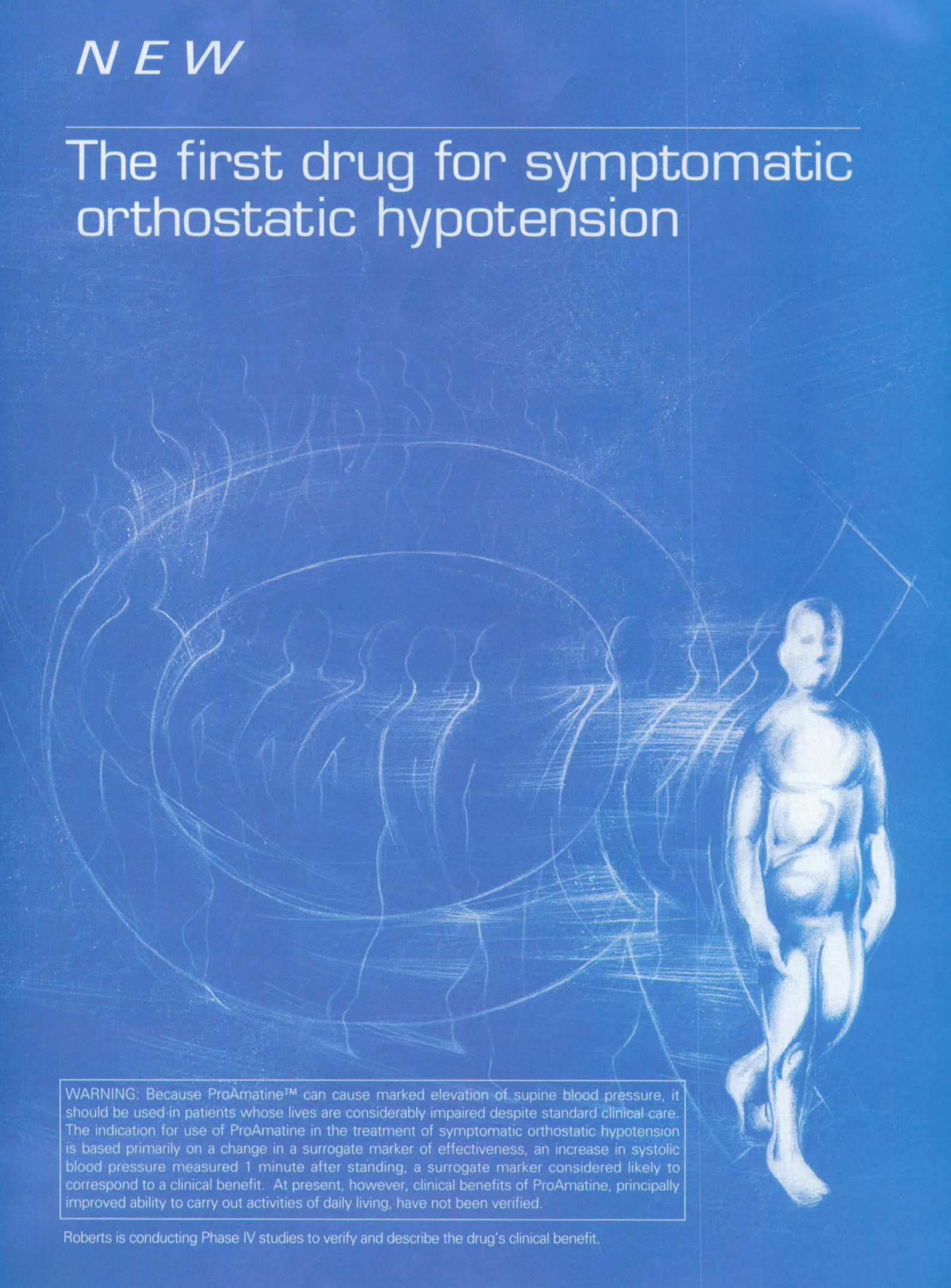
**DOSE MUST BE INDIVIDUALIZED.** The initial dosage of CARDURA in hypertensive patients is 1 mg given once daily. This starting dose is intended to minimize the frequency of postural hypotension and first dose syncope associated with CARDURA. Postural effects are most likely to occur between 2 and 6 hours after a dose. Therefore blood pressure measurements should be taken during this time period after the first dose and with each increase in dose. Depending on the individual patient's standing blood pressure response (based on measurements taken at 2-6 hours postdose and 24 hours postdose), dosage may then be increased to 2 mg and thereafter if necessary to 4 mg, 8 mg and 16 mg to achieve the desired reduction in blood pressure. Increases in dose beyond 4 mg increase the likelihood of excessive postural effects including syncope, postural dizziness/vertigo, postural hypotension. At a titrated dose of 16 mg once daily the frequency of postural effects is about 12% compared to 3% for placebo.

More detailed professional information available on request.



*NEW*

# The first drug for symptomatic orthostatic hypotension



**WARNING:** Because ProAmatine™ can cause marked elevation of supine blood pressure, it should be used in patients whose lives are considerably impaired despite standard clinical care. The indication for use of ProAmatine in the treatment of symptomatic orthostatic hypotension is based primarily on a change in a surrogate marker of effectiveness, an increase in systolic blood pressure measured 1 minute after standing, a surrogate marker considered likely to correspond to a clinical benefit. At present, however, clinical benefits of ProAmatine, principally improved ability to carry out activities of daily living, have not been verified.

Roberts is conducting Phase IV studies to verify and describe the drug's clinical benefit.

**NEW**

*Pharmacologic Support for Patients With*

# **α ProAm (midodrine)**

Tablets of 2.5 mg and 5 mg

## **A unique alpha-adrenergic agent<sup>1</sup>**

- Does not readily cross blood-brain barrier<sup>1</sup>  
.....
- Does not increase circulating volume<sup>1</sup>  
.....
- Duration of action ≈3 hours<sup>3</sup>

\*Because ProAmatine can cause marked elevation of supine blood pressure, it should be used in patients whose lives are considerably impaired despite standard clinical care. ProAmatine should be used in patients who have not responded to standard clinical care such as support stockings, sleeping in the head-up tilt position, and increased salt intake.

ProAmatine is contraindicated in patients with severe organic heart disease, acute renal disease, urinary retention, pheochromocytoma, or thyrotoxicosis and should not be used by patients with persistent and excessive supine hypertension.

See brief summary of full Prescribing Information on last page.

**S Y M P T O M S :     D I Z Z I N E S S**



***Symptomatic Orthostatic Hypotension (OH)\****

# atine<sup>TM</sup> hydrochloride)

—increases standing blood pressure<sup>2</sup>

—minimal CNS side effects<sup>3</sup>

—avoids the risks of volume-expanding therapy

—offers the safety and flexibility to increase blood pressure only during the active daytime hours

*Note:* The last dose should be taken before 6 PM to reduce the risk of supine hypertension, which occurred in 7% of patients in a 3-week, placebo-controlled trial.<sup>3</sup>

***Controls blood pressure  
fall when your patients rise***



S Y N C O P E



# ProAmatine®

## (midodrine hydrochloride)

Tablets of 2.5 mg and 5 mg

### Controls blood pressure fall when your patients rise

**References:** 1. McTavish D, Goa KL. Midodrine. A review of its pharmacological properties and therapeutic use in orthostatic hypotension and secondary hypotensive disorders. *Drugs*. 1989;38:757-777. 2. Data on file, Roberts Pharmaceutical Corporation. 3. Prescribing Information, ProAmatine®.

**Brief Summary** Consult the package insert for complete Prescribing Information.

**WARNING:** Because ProAmatine can cause marked elevation of supine blood pressure, it should be used in patients whose lives are considerably impaired despite standard clinical care. The indication for use of ProAmatine in the treatment of symptomatic orthostatic hypotension is based primarily on a change in a surrogate marker of effectiveness, an increase in systolic blood pressure measured one minute after standing, a surrogate marker considered likely to correspond to a clinical benefit. At present, however, clinical benefits of ProAmatine, principally improved ability to carry out activities of daily living, have not been verified.

**Clinical Studies:** Midodrine has been studied in 3 principal controlled trials, one of 3-weeks duration and 2 of 1 to 2 days duration. All studies were randomized, double-blind and parallel-design trials in patients with orthostatic hypotension of any etiology and supine-to-standing fall of systolic blood pressure of at least 15 mmHg accompanied by at least moderate dizziness/lightheadedness. Patients with pre-existing sustained supine hypertension above 180/110 mmHg were routinely excluded. In a 3-week study in 170 patients, most previously untreated with midodrine, the midodrine-treated patients (10 mg t.i.d., with the last dose not later than 6 P.M.) had significantly higher (by about 20 mmHg) 1-minute standing systolic pressure 1 hour after dosing (blood pressures were not measured at other times) for all 3 weeks. After week 1, midodrine-treated patients had small improvements in dizziness/lightheadedness/unsteadiness scores and global evaluations, but these effects were made difficult to interpret by a high early drop-out rate (about 25% vs 5% on placebo). Supine and sitting blood pressure rose 16/8 and 20/10 mmHg, respectively, on average. In a 2-day study, after open-label midodrine, known midodrine responders received midodrine 10 mg or placebo at 0, 3, and 6 hours. One-minute standing systolic blood pressures were increased 1 hour after each dose by about 15 mmHg and 3 hours after each dose by about 12 mmHg; 3-minute standing pressures were increased also at 1, but not at 3, hours after dosing. There were increases in standing time seen intermittently 1 hour after dosing, but not at 3 hours. In a 1-day, dose-response trial, single doses of 0, 2.5, 10, and 20 mg of midodrine were given to 25 patients. The 10- and 20-mg doses produced increases in standing 1-minute systolic pressure of about 30 mmHg at 1 hour; the increase was sustained in part for 2 hours after 10 mg and 4 hours after 20 mg. Supine systolic pressure was  $\geq 200$  mmHg in 22% of patients on 10 mg and 45% of patients on 20 mg; elevated pressures often lasted 6 hours or more.

**INDICATIONS AND USAGE:** ProAmatine is indicated for the treatment of symptomatic orthostatic hypotension (OH). Because ProAmatine can cause marked elevation of supine blood pressure (BP  $> 200$  mmHg systolic), it should be used in patients whose lives are considerably impaired despite standard clinical care, including non-pharmacologic treatment (such as support stockings), fluid expansion, and lifestyle alterations. The indication is based on ProAmatine's effect on increases in 1-minute standing systolic blood pressure, a surrogate marker considered likely to correspond to a clinical benefit. At present, however, clinical benefits of ProAmatine, principally improved ability to perform life activities, have not been established. Further clinical trials are underway to verify and describe the clinical benefits of ProAmatine. After initiation of treatment, ProAmatine should be continued only for patients who report significant symptomatic improvement.

**CONTRAINDICATIONS:** ProAmatine is contraindicated in patients with severe organic heart disease, acute renal disease, urinary retention, pheochromocytoma or thyrotoxicosis. ProAmatine should not be used in patients with persistent and excessive supine hypertension.

**WARNINGS:** **Supine Hypertension:** The most potentially serious adverse reaction associated with ProAmatine therapy is marked elevation of supine arterial blood pressure (supine hypertension). Systolic pressure of about 200 mmHg were seen overall in about 13.4% of patients given 10 mg of ProAmatine. Systolic elevations of this degree were most likely to be observed in patients with relatively elevated pretreatment systolic blood pressures (mean 170 mmHg). There is no experience in patients with initial supine systolic pressure above 180 mmHg, as those patients were excluded from the clinical trials. Use of ProAmatine in such patients is not recommended. Sitting blood pressures were also elevated by ProAmatine therapy. It is essential to monitor supine and sitting blood pressures in patients maintained on ProAmatine.

#### PRECAUTIONS

**General:** The potential for supine and sitting hypertension should be evaluated at the beginning of ProAmatine therapy. Supine hypertension can often be controlled by preventing the patient from becoming fully supine, i.e., sleeping with the head of the bed elevated. The patient should be cautioned to report symptoms of supine hypertension immediately. Symptoms may include cardiac awareness, pounding in the ears, headache, blurred vision, etc. The patient should be advised to discontinue the medication immediately if supine hypertension persists. Blood pressure should be monitored carefully when ProAmatine is used concomitantly with other agents that cause vasoconstriction, such as phenylephrine, ephedrine, dihydroergotamine, phenylpropranolamine, or pseudoephedrine. A slight slowing of the heart rate may occur after administration of ProAmatine, primarily due to vagal reflex. Caution should be exercised when ProAmatine is used concomitantly with cardiac glycosides (such as digitalis), psychopharmacologic agents, beta blockers or other agents that directly or indirectly reduce heart rate. Patients who experience any signs or symptoms suggesting bradycardia (pulse slowing, increased dizziness, syncope, cardiac awareness) should be advised to discontinue ProAmatine and should be re-evaluated. ProAmatine should be used cautiously in patients with urinary retention problems, as desglymidodrine acts on the alpha-adrenergic receptors of the bladder neck. ProAmatine should be used with caution in orthostatic hypotensive patients who are also diabetic, as well as those with a history of visual problems who are also taking fludrocortisone acetate, which is known to cause an increase in intraocular pressure and glaucoma. ProAmatine use has not been studied in patients with renal impairment. Because desglymidodrine is eliminated via the kidneys, and higher blood levels would be expected in such patients, ProAmatine should be used with caution in patients with renal impairment, with a starting dose of 2.5 mg (see **DOSE AND ADMINISTRATION**). Renal function should be assessed prior to initial use of ProAmatine. ProAmatine use has not been studied in patients with hepatic impairment. ProAmatine should be used with caution in patients with hepatic impairment, as the liver has a role in the metabolism of midodrine.

**Information for Patients:** Patients should be told that certain agents in over-the-counter products, such as cold remedies and diet aids, can elevate blood pressure, and therefore, should be used cautiously with ProAmatine, as they may enhance or potentiate the pressor effects of ProAmatine (see **Drug Interactions**). Patients should also be made aware of the possibility of supine hypertension. They should be told to avoid taking their dose if they are to be supine for any length of time, i.e., they should take their last daily dose of ProAmatine 3 to 4 hours before bedtime to minimize nighttime supine hypertension.

**Laboratory Tests:** Since desglymidodrine is eliminated by the kidneys and the liver has a role in its metabolism, evaluation of the patient should include assessment of renal and hepatic function prior to initiating therapy and subsequently, as appropriate.

**Drug Interactions:** When administered concomitantly with ProAmatine, cardiac glycosides may enhance or precipitate bradycardia, A.V. block or arrhythmia. The use of drugs that stimulate alpha-adrenergic receptors (e.g., phenylephrine, pseudoephedrine, ephedrine, phenylpropranolamine or dihydroergotamine) may enhance or potentiate the pressor effects of ProAmatine. Therefore, caution should be used when ProAmatine is administered concomitantly with agents that cause vasoconstriction. ProAmatine has been used in patients concomitantly treated with salt-retaining steroid therapy (i.e., fludrocortisone acetate), with or without salt supplementation. The potential for supine hypertension should be carefully monitored in these patients and may be minimized by either reducing the dose of fludrocortisone acetate or decreasing the salt intake prior to initiation of treatment with ProAmatine. Alpha-adrenergic blocking agents, such as prazosin, terazosin, and doxazosin, can antagonize the effects of ProAmatine.

**Potential for Drug Interactions:** It appears possible, although there is no supporting experimental evidence, that the high renal clearance of desglymidodrine (a base) is due to active tubular secretion by the base-secreting system also responsible for the secretion of such drugs as metformin, cimetidine, ranitidine, procainamide, triamterene, flecainide, and quinidine. Thus there may be a potential for drug-drug interactions with these drugs.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies have been conducted in rats and mice at dosages of 3 to 4 times the maximum recommended daily human dose on a mg/m<sup>2</sup> basis, with no indication of carcinogenic effects related to ProAmatine. Studies investigating the mutagenic potential of ProAmatine revealed no evidence of mutagenicity. Other than the dominant lethal assay in male mice, where no impairment of fertility was observed, there have been no studies on the effects of ProAmatine on fertility. **Pregnancy:** *Pregnancy Category C.* ProAmatine increased the rate of embryo resorption, reduced fetal body weight in rats and rabbits, and decreased fetal survival in rabbits when given in doses 13 (rat) and 7 (rabbit) times the maximum human dose based on body surface area (mg/m<sup>2</sup>). There are no adequate and well-controlled studies in pregnant women. ProAmatine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No teratogenic effects have been observed in studies in rats and rabbits. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ProAmatine is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **ADVERSE REACTIONS:** The most frequent adverse reactions seen in controlled trials were supine and sitting hypertension; paresthesia and pruritus, mainly of the scalp; goosebumps; chills; urinary urge; urinary retention and urinary frequency. The frequency of these events in a 3-week placebo-controlled trial is shown in the following table:

Event	Placebo (n=88)		Midodrine (n=82)	
	# of reports	% of patients	# of reports	% of patients
Total # of reports	22		77	
Paresthesia <sup>1</sup>	4	4.5	15	18.3
Piloerection	0		11	13.4
Dysuria <sup>2</sup>	0	0	11	13.4
Pruritus <sup>3</sup>	2	2.3	10	12.2
Supine hypertension <sup>4</sup>	0	0	6	7.3
Chills	0	0	4	4.9
Pain <sup>5</sup>	0	0	4	4.9
Rash	1	1.1	2	2.4

<sup>1</sup> Includes hyperesthesia and scalp paresthesia

<sup>2</sup> Includes dysuria (1), increased urinary frequency (2), impaired urination (1), urinary retention (5), urinary urgency (2)

<sup>3</sup> Includes scalp pruritus

<sup>4</sup> Includes patients who experienced an increase in supine hypertension

<sup>5</sup> Includes abdominal pain and pain increase

Less frequent adverse reactions were headache; feeling of pressure/fullness in the head; vasodilation/flushing face; confusion/thinking abnormality; dry mouth; nervousness/anxiety and rash. Other adverse reactions that occurred rarely were visual field defect; dizziness; skin hyperesthesia; insomnia; somnolence; erythema multiforme; canker sore; dry skin; dysuria; impaired urination; asthenia; backache; pyrosis; nausea; gastrointestinal distress; flatulence and leg cramps. The most potentially serious adverse reaction associated with ProAmatine therapy is supine hypertension. The feelings of paresthesia, pruritus, piloerection and chills are pilomotor reactions associated with the action of midodrine on the alpha-adrenergic receptors of the hair follicles. Feelings of urinary urgency, retention and frequency are associated with the action of midodrine on the alpha-receptors of the bladder neck.

**OVERDOSEAGE:** Symptoms of overdose could include hypertension, piloerection (goosebumps), a sensation of coldness and urinary retention. There are 2 reported cases of overdose of ProAmatine, both in young males. One patient ingested ProAmatine drops, 250 mg, experienced systolic blood pressure of greater than 200 mmHg, was treated with an IV injection of 20 mg of phentolamine, and was discharged the same night without any complaints. The other patient ingested 205 mg of ProAmatine (41 5-mg tablets), and was found lethargic and unable to talk, unresponsive to voice but responsive to painful stimuli, hypertensive and bradycardic. Gastric lavage was performed, and the patient recovered fully by the next day without sequelae. The single doses that would be associated with symptoms of overdose or would be potentially life-threatening are unknown. The oral LD<sub>50</sub> is approximately 30 to 50 mg/kg in rats, 675 mg/kg in mice, and 125 to 180 mg/kg in dogs. Desglymidodrine is dialyzable. Recommended general treatment, based on the pharmacology of the drug, includes induced emesis and administration of alpha-sympatholytic drugs (e.g., phentolamine).

**DOSE AND ADMINISTRATION:** The recommended dose of ProAmatine is 10 mg, 3 times daily. Dosing should take place during the daytime hours when the patient needs to be upright, pursuing the activities of daily life. A suggested dosing schedule of approximately 4-hour intervals is as follows: shortly before or upon arising in the morning, midday, and late afternoon (not later than 6 P.M.). Doses may be given in 3-hour intervals, if required, to control symptoms, but not more frequently. Single doses as high as 20 mg have been given to patients, but severe and persistent systolic supine hypertension occur at a high rate (about 45%) at this dose. In order to reduce the potential for supine hypertension during sleep, ProAmatine should not be given after the evening meal or less than 4 hours before bedtime. Total daily doses greater than 30 mg have been tolerated by some patients, but their safety and usefulness have not been studied systematically or established. Because of the risk of supine hypertension, ProAmatine should be continued only in patients who appear to attain symptomatic improvement during initial treatment. The supine and standing blood pressure should be monitored regularly, and the administration of ProAmatine should be stopped if supine blood pressure increases excessively. Because desglymidodrine is excreted renally, dosing in patients with abnormal renal function should be cautious; although this has not been systematically studied, it is recommended that treatment of these patients be initiated using 2.5-mg doses. Dosing in children has not been adequately studied. Blood levels of midodrine and desglymidodrine were similar when comparing levels in patients 65 or older vs. younger than 65 and when comparing males vs. females, suggesting dose modifications for these groups are not necessary.

**HOW SUPPLIED:** ProAmatine is supplied as 2.5-mg and 5-mg tablets for oral administration. The 2.5-mg tablet is white, round, and biplanar, with a bevelled edge, and is scored on 1 side with "RPC" above and "2.5" below the score, and "003" on the other side. The 5-mg tablet is orange, round, and biplanar, with a bevelled edge, and is scored on 1 side with "RPC" above and "5" below the score, and "004" on the other side.

2.5-milligram Tablets: NDC 54092-003-01 Bottle of 100  
5-milligram Tablets: NDC 54092-004-01 Bottle of 100

Store from 15°C to 25°C (59°F to 77°F).

**CAUTION: Keep this and all medication out of the reach of children.**



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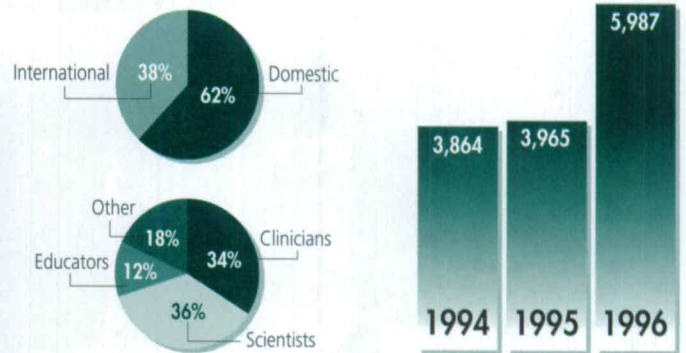
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## GUEST EDITORIAL

- Insulin 1996 — 75 Years After its Discovery** *J. Jervell* ..... 847

## ORIGINAL ARTICLES

- Detection of Sight-threatening Diabetic Eye Disease** *G. P. Leese, D. M. Broadbent, S. P. Harding, J. P. Vora* ..... 850
- Human Studies with Glucagon-like-peptide-1: Potential of the Gut Hormone for Clinical Use** *M. M. Byrne, B. Göke* ..... 854
- The Diagnosis of 'Pathological Hyperglycaemia' in Gestational Diabetes in a High Risk Obstetric Population** *H. A. Nasrat, M. S. Ardawi, B. A. Abalkhail* ..... 861
- Nutrition in Pregnancy and the Concentrations of Proinsulin, 32–33 Split Proinsulin, Insulin, and C-peptide in Cord Plasma** *K. M. Godfrey, S. Robinson, C. N. Hales, D. J. P. Barker, C. Osmond, K. P. Taylor* ..... 868
- Are Body Mass or Insulin Resistance Independently Associated with Cardiovascular Risk Factors in Non-diabetic Elderly Nigerians?** *C. E. Ezenwaka, A. O. Akanji, N. Unwin, K. G. M. M. Alberti* ..... 874
- Effects of a Purified Micronized Flavonoid Fraction on Capillary Filtration in Diabetic Patients** *P. E. Valensi, A. Behar, M. M. de Champvallins, M. Attalah, F. C. Boulakia, J-R. Attali* ..... 882
- Low Prevalence of Microalbuminuria in Young Italian Insulin-dependent Diabetic Patients with Short Duration of Disease: a Population-based Study** *G. Bruno, G. Pagano* ..... 889
- Self-monitoring of Triglycerides by Type 2 Diabetic Patients: Variability in Fasting and Postprandial Levels** *M. W. Stewart, C. Albers, M. F. Laker, A. Hattemer, K. G. M. M. Alberti, V. Connolly, C. M. Kesson* ..... 894
- Socio-economic Status and Membership of the British Diabetic Association in Scotland** *V. Connolly, C. M. Kesson* ..... 898
- A Population Association Study of Four Candidate Genes (Hexokinase II, Glucagon-like Peptide-1 Receptor, Fatty Acid Binding Protein-2, and Apolipoprotein C-II) with Type 2 Diabetes and Impaired Glucose Tolerance in Japanese Subjects** *T. Yagi, S.-I. Nishi, S. Hinata, M. Murakami, T. Yoshimi* ..... 902

## CASE REPORT

- Severe Ketoacidosis Complicated by 'Ecstasy' Ingestion and Prolonged Exercise** *H. R. Seymour, D. Gilman, J. D. Quin* ..... 908

## CONFERENCE REPORT

- CIBA Foundation Meeting on Enteroviruses and Early Childhood Diabetes** *K. W. Taylor* ..... 910

## SYMPOSIUM REPORT

- The Diabetic Foot 1996** *A. L. Carrington, H. Connor, A. J. M. Boulton* ..... 912

## BOOK REVIEWS

- Molecular Biology of Diabetes II. Insulin Action, Effects on Gene Expression and Regulation, and Glucose Transport**, edited by *B. Draznin, D. LeRoith* Reviewed by *S. Kumar* ..... 915
- Understanding Diabetes**, by *R. W. Bilous* Reviewed by *C. Fox* ..... 915

## LETTERS

- Erectile Dysfunction in Men with and without Diabetes Mellitus: a Comparative Study** *R. E. J. Ryder* ..... 916
- Reply from J. Bancroft** ..... 916
- Hypoglycaemia and Self-care Behaviour in IDDM Adults in Bulgaria** *D. J. Cox, B. Kovatchev, D. J. Koev, S. D. Datchev, L. A. Koeva* ..... 916
- The Glucose Challenge Test: Different Drink Dilutions** *R. Davey* ..... 917
- Shared Care for Diabetic Patients in Hungary** *G. Jermendy* ..... 919

DM Diary, 842 • Errata, 846



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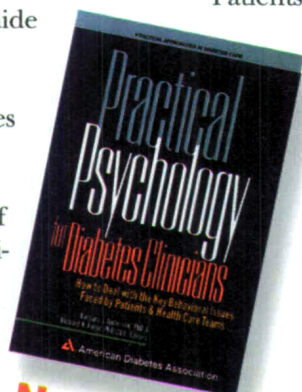
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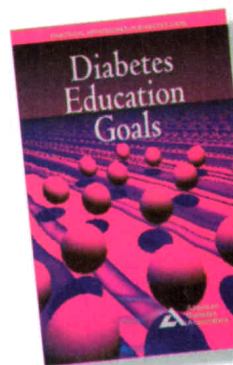
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