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Diabetes Care

VOLUME 15 NUMBER 3

Review Issue

MARCH 1992

Review Articles

American Diabetes Association®

ISSN 0149-5992

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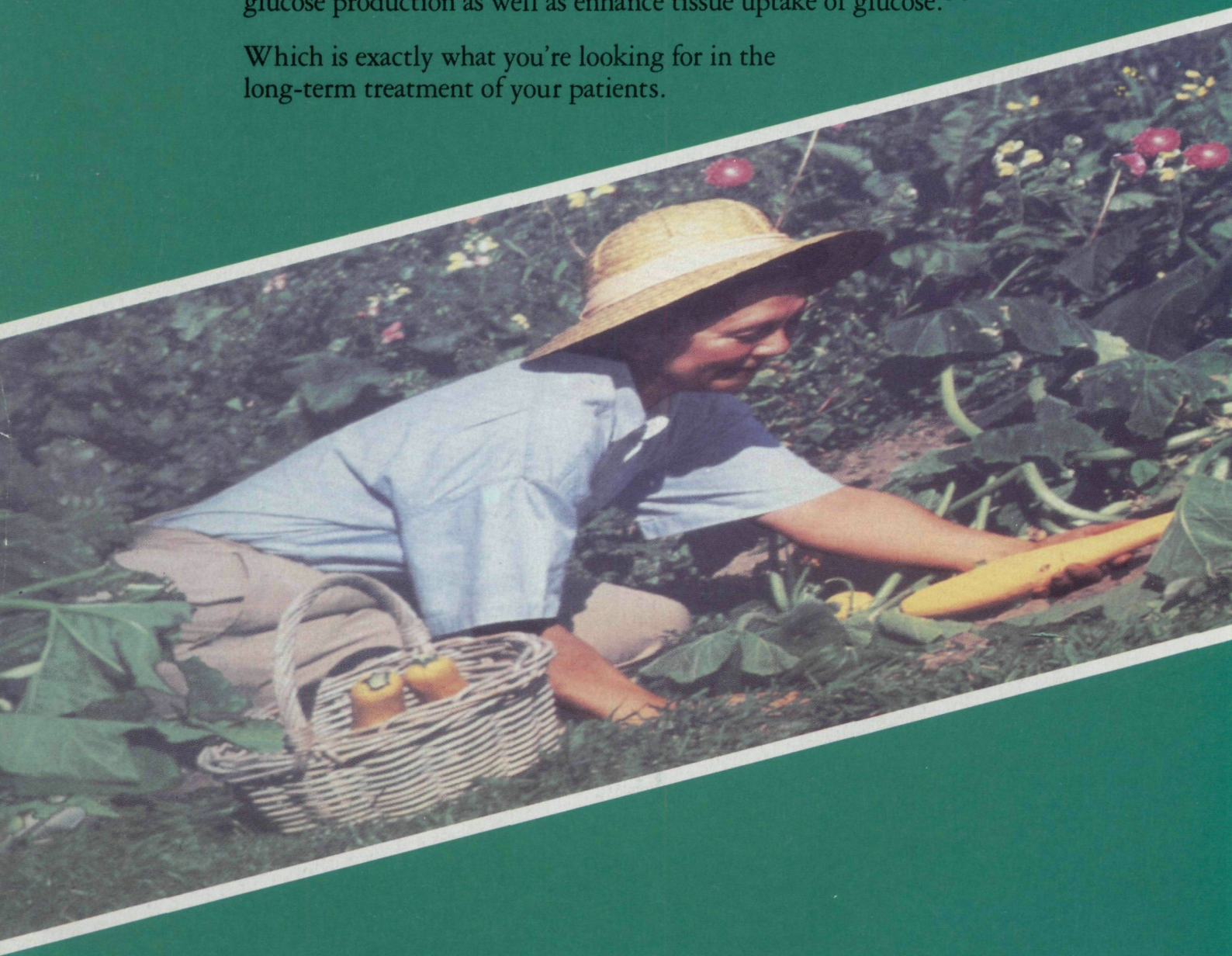

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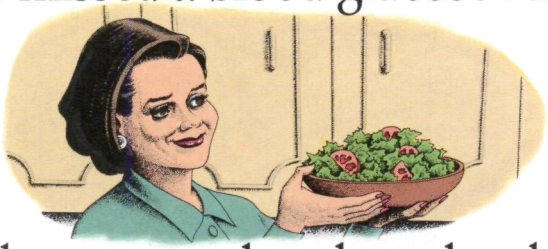
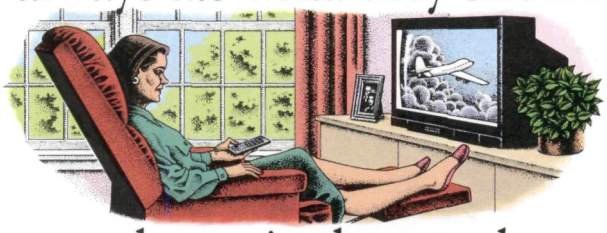


always ate what they should...



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THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

VOLUME 15 NUMBER 3

Diabetes Care

Diabetes Care publishes original articles and reviews of human and clinical research intended to increase knowledge, stimulate research, and promote better management of people with diabetes mellitus. Emphasis is on human studies reporting on the pathophysiology and treatment of diabetes and its complications; genetics; epidemiology; psychosocial adaptation; education; and the development, validation, and application of accepted and new therapies. Topics covered are of interest to clinically oriented physicians, researchers, epidemiologists, psychologists, diabetes educators, and other professionals.

All manuscripts and other editorial correspondence should be sent by first class mail to Allan L. Drash, MD, Editor, *Diabetes Care*, Children's Hospital, Rangos Research Center, 3705 Fifth Avenue, Pittsburgh, PA 15213. Manuscripts and correspondence regarding review articles should be sent to Ralph A. DeFronzo, MD, Review Editor, *Diabetes Care*, Department of Medicine, Division of Diabetes, UT-HSCSA, 7703 Floyd Curl Drive, San Antonio, TX 78284.

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Manuscripts should be prepared in accord with the requirements specified in the document "Uniform Requirements for Manuscripts Submitted to Biomedical Journals," *Annals of Internal Medicine* 96:766–71, 1982. An "Instructions for Authors" page containing specifications for manuscript preparation appears in the January and July issues of each volume.

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American Diabetes Association.

Review Articles

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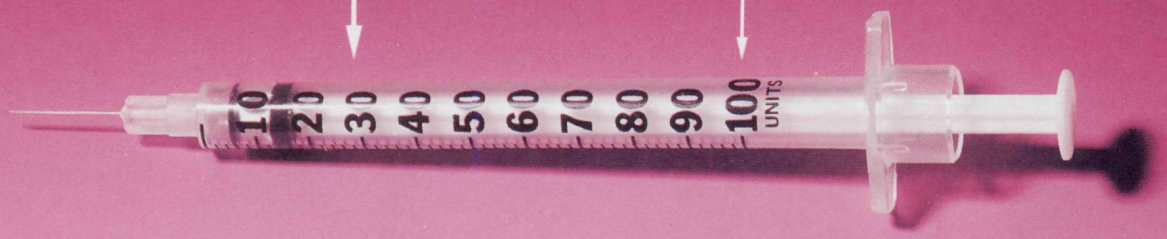

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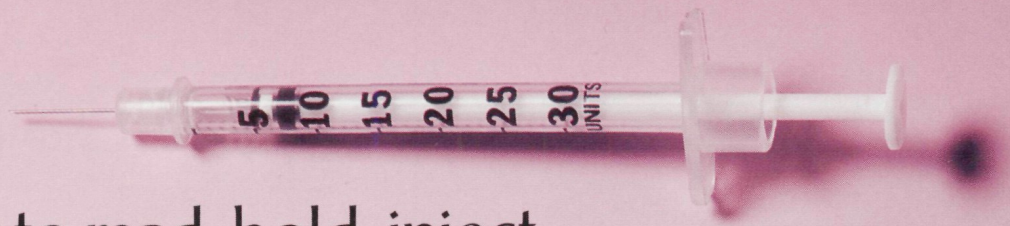

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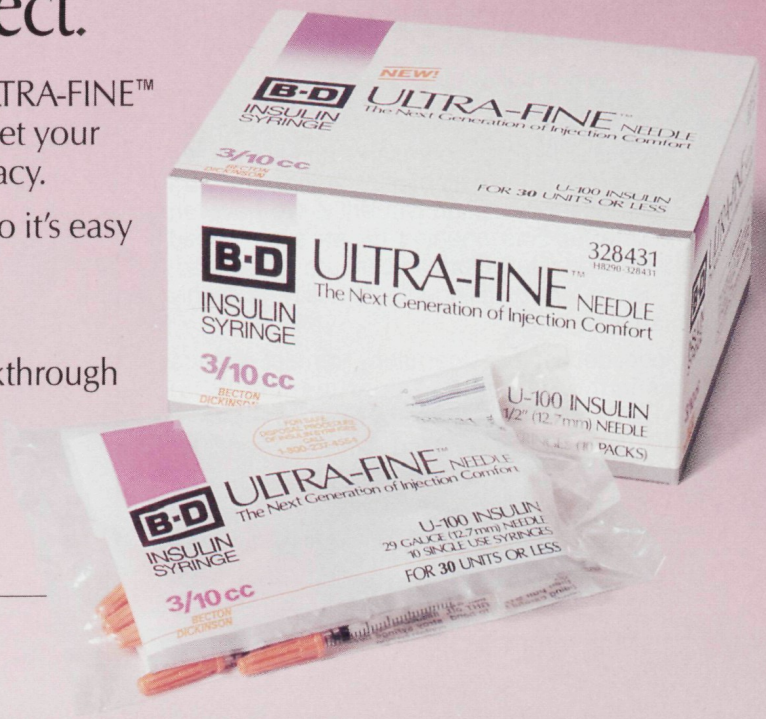

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Evaluation of the hypertensive patient should always include assessment of renal function (see Dosage and Administration). Angioedema has been reported with ACE inhibitors, including ZESTRIL (see Warnings).

*The antihypertensive effect may diminish at the end of the dosing interval.
†Calculated from prescription refill data from patients enrolled in the Tenormin® (atenolol) Wellspring Service.[1]

Please see adjacent page for brief summary of prescribing information.

Reference: 1. Sclar DA, Chin A, Skaer TL, Okamoto MP, Nakahiro RK, Gill MA. Effect of health education in promoting prescription refill compliance among patients with hypertension. *Clin Ther.* 1991;13:489-495.

ZESTRIL® (LISINOPRIL)

Available in 5 mg (scored), 10 mg, 20 mg, 40 mg tablets

(FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE INSERT.)

INDICATIONS AND USAGE: ZESTRIL is indicated for the treatment of hypertension. It may be used alone as initial therapy or concomitantly with other classes of antihypertensive agents.

In using ZESTRIL, consideration should be given to the fact that another angiotensin converting enzyme inhibitor, captopril, has caused agranulocytosis, particularly in patients with renal impairment or collagen vascular disease, and that available data are insufficient to show that ZESTRIL does not have a similar risk. (See WARNINGS.)

CONTRAINDICATIONS: ZESTRIL is contraindicated in patients who are hypersensitive to this product and in patients with a history of angioedema related to previous treatment with an angiotensin converting enzyme inhibitor.

WARNINGS: Angioedema: Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with angiotensin converting enzyme inhibitors, including ZESTRIL. In such cases, ZESTRIL should be promptly discontinued and appropriate therapy and monitoring should be provided until complete and sustained resolution of signs and symptoms has occurred. In instances where swelling has been confined to the face and lips the condition has generally resolved without treatment, although antihistamines have been useful in relieving symptoms. Angioedema associated with laryngeal edema may be fatal. **Where there is involvement of the tongue, glottis or larynx likely to cause airway obstruction, appropriate therapy, eg, subcutaneous epinephrine solution 1:1000 (0.3 mL to 0.5 mL) and/or measures necessary to ensure a patent airway should be promptly provided. (See ADVERSE REACTIONS.)**

Hypotension: Excessive hypotension was rarely seen in uncomplicated hypertensive patients but is a possible consequence of the use with ZESTRIL in salt/volume-depleted persons, such as those treated vigorously with diuretics or patients on dialysis. (See PRECAUTIONS, Drug Interactions and ADVERSE REACTIONS.) In patients with severe congestive heart failure, with or without associated renal insufficiency, excessive hypotension has been observed and may be associated with oliguria and/or progressive azotemia, and rarely with acute renal failure and/or death. Because of the potential fall in blood pressure in these patients, therapy should be started under very close medical supervision. Such patients should be followed closely for the first two weeks of treatment and whenever the dose of ZESTRIL and/or diuretic is increased. Similar considerations apply to patients with ischemic heart or cerebrovascular disease in whom an excessive fall in blood pressure could result in a myocardial infarction or cerebrovascular accident.

If hypotension occurs, the patient should be placed in supine position and, if necessary, receive an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further doses which usually can be given without difficulty once the blood pressure has increased after volume expansion.

Neutropenia/Agranulocytosis: Another angiotensin converting enzyme inhibitor, captopril, has been shown to cause agranulocytosis and bone marrow depression, rarely in uncomplicated patients but more frequently in patients with renal impairment especially if they also have a collagen vascular disease. Available data from clinical trials of ZESTRIL are insufficient to show that ZESTRIL does not cause agranulocytosis at similar rates. Marketing experience has revealed rare cases of neutropenia and bone marrow depression in which a causal relationship to lisinopril cannot be excluded. Periodic monitoring of white blood cell counts in patients with collagen vascular disease and renal disease should be considered.

Fetal/Neonatal Morbidity and Mortality: ACE inhibitors, including ZESTRIL, can cause fetal and neonatal morbidity and mortality when administered to pregnant women.

Lisinopril crosses the human placenta. When ACE inhibitors have been used during the second and third trimesters of pregnancy, there have been reports of hypotension, renal failure, skull hypoplasia, and/or death in the newborn. Oligohydramnios has also been reported, presumably representing decreased renal function in the fetus; limb contractures, craniofacial deformities, hypoplastic lung development and intrauterine growth retardation have been reported in association with oligohydramnios. Patients who do require ACE inhibitors during the second and third trimesters of pregnancy should be apprised of the potential hazards to the fetus, and frequent ultrasound examinations should be performed to look for oligohydramnios. If oligohydramnios is observed, ZESTRIL should be discontinued unless it is considered life-saving for the mother.

Other potential risks to the fetus/neonate exposed to ACE inhibitors include: intrauterine growth retardation, prematurity, patent ductus arteriosus; fetal death has also been reported. It is not clear, however, whether these reported events are related to ACE inhibition or the underlying maternal disease. It is not known whether exposure limited to the first trimester can adversely affect fetal outcome.

Infants exposed in utero to ACE inhibitors should be closely monitored for hypotension, oliguria, and hyperkalemia. If oliguria occurs, attention should be directed toward support of blood pressure and renal perfusion.

Another ACE inhibitor, enalapril, has been removed from the neonatal circulation by peritoneal dialysis and theoretically may be removed by exchange transfusion, although there is no experience with the latter procedure. There is no experience with either of these procedures for removing lisinopril or other ACE inhibitors from the neonatal circulation.

Lisinopril was not teratogenic in mice treated on days 6-15 of gestation with up to 1,000 mg/kg/day (625 times the maximum recommended human dose). There was an increase in fetal resorptions at doses down to 100 mg/kg; at doses of 1,000 mg/kg this was prevented by saline supplementation. There was no fetotoxicity or teratogenicity in rats treated with up to 300 mg/kg/day (188 times the maximum recommended dose) of lisinopril at days 6-17 of gestation. In rats receiving lisinopril from day 15 of gestation through day 21 postpartum, there was an increased incidence in pup deaths on days 2-7 postpartum and a lower average body weight of pups on day 21 postpartum. The increase in pup deaths and decrease in pup weight did not occur with maternal saline supplementation.

Lisinopril, at doses up to 1 mg/kg/day, was not teratogenic when given throughout the organogenic period in saline supplemented rabbits. Saline supplementation (physiologic saline in place of tap water) was used to eliminate maternotoxic effects and enable evaluation of the teratogenic potential at the highest possible dosage level. The rabbit has been shown to be extremely sensitive to angiotensin converting enzyme inhibitors (captopril and enalapril) with maternal and fetotoxic effects apparent at or below the recommended therapeutic dosage levels in man.

Fetotoxicity was demonstrated in rabbits by an increased incidence of fetal resorptions at an oral dose of lisinopril of 1 mg/kg/day and by an increased incidence of incomplete ossification at the lowest dose tested (0.1 mg/kg/day). A single intravenous dose of 15 mg/kg of lisinopril administered to pregnant rabbits on gestation days 16, 21 or 26 resulted in 88% to 100% fetal death.

If ZESTRIL is used during pregnancy or if the patient becomes pregnant while taking ZESTRIL, the patient should be apprised of the potential hazards to the fetus.

PRECAUTIONS: General: Impaired Renal Function: As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may be anticipated in susceptible individuals. In patients with severe congestive heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin converting enzyme inhibitors, including ZESTRIL, may be associated with oliguria and/or progressive azotemia and rarely with acute renal failure and/or death.

In hypertensive patients with unilateral or bilateral renal artery stenosis, increases in blood urea nitrogen and serum creatinine may occur. Experience with another angiotensin converting enzyme inhibitor suggests that these increases are usually reversible upon discontinuation of ZESTRIL and/or diuretic therapy. In such patients, renal function should be monitored during the first few weeks of therapy.

Some hypertensive patients with no apparent pre-existing renal vascular disease have developed increases in blood urea nitrogen and serum creatinine, usually minor and transient, especially when ZESTRIL has been given concomitantly with a diuretic. This is more likely to occur in patients with pre-existing renal impairment. Dosage reduction of ZESTRIL and/or discontinuation of the diuretic may be required.

Evaluation of the hypertensive patient should always include assessment of renal function. (See DOSAGE AND ADMINISTRATION.)

Hyperkalemia: In clinical trials hyperkalemia (serum potassium greater than 5.7 mEq/L) occurred in approximately 2.2% of hypertensive patients and 4.0% of patients with congestive heart failure. In most cases these were isolated values which resolved despite continued therapy. Hyperkalemia was a cause of discontinuation of therapy in approximately 0.1% of hypertensive patients. Risk factors for the development of hyperkalemia include renal insufficiency, diabetes mellitus, and the concomitant use of potassium-sparing diuretics, potassium supplements and/or potassium-containing salt substitutes, which should be used cautiously, if at all, with ZESTRIL. (See Drug Interactions.)

Cough: Cough has been reported with the use of ACE inhibitors. Characteristically, the cough is nonproductive, persistent and resolves after discontinuation of therapy. ACE inhibitor-induced cough should be considered as part of the differential diagnosis of cough.

Surgery/Anesthesia: In patients undergoing major surgery or during anesthesia with agents that produce hypotension, ZESTRIL may block angiotensin II formation secondary to compensatory renin release. If hypotension occurs and is considered to be due to this mechanism, it can be corrected by volume expansion.

Information for Patients: Angioedema: Angioedema, including laryngeal edema, may occur especially following the first dose of ZESTRIL. Patients should be so advised and told to report immediately any signs or symptoms suggesting angioedema (swelling of face, extremities, eyes, lips, tongue, difficulty in swallowing or breathing) and to take no more drug until they have consulted with the prescribing physician.

Symptomatic Hypotension: Patients should be cautioned to report lightheadedness especially during the first few days of therapy. If actual syncope occurs, the patient should be told to discontinue the drug until they have consulted with the prescribing physician.

All patients should be cautioned that excessive perspiration and dehydration may lead to an excessive fall in blood pressure because of reduction in fluid volume. Other causes of volume depletion such as vomiting or diarrhea may also lead to a fall in blood pressure; patients should be advised to consult with their physician.

Hyperkalemia: Patients should be told not to use salt substitutes containing potassium without consulting their physician.

Neutropenia: Patients should be told to report promptly any indication of infection (eg, sore throat, fever) which may be a sign of neutropenia.

NOTE: As with many other drugs, certain advice to patients being treated with ZESTRIL is warranted. This information is intended to aid in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects.

DRUG INTERACTIONS: Hypotension - Patients on Diuretic Therapy: Patients on diuretics and especially those in whom diuretic therapy was recently instituted, may occasionally experience an excessive reduction of blood pressure after initiation of therapy with ZESTRIL. The possibility of hypotensive effects with ZESTRIL can be minimized by either discontinuing the diuretic or increasing the salt intake prior to initiation of treatment with ZESTRIL. If it is necessary to continue the diuretic, initiate therapy with ZESTRIL at a dose of 5 mg daily, and provide close medical supervision after the initial dose for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS, and DOSAGE AND ADMINISTRATION.) When a diuretic is added to the therapy of a patient receiving ZESTRIL, an additional antihypertensive effect is usually observed. Studies with ACE inhibitors in combination with diuretics indicate that the dose of the ACE inhibitor can be reduced when it is given with a diuretic. (See DOSAGE AND ADMINISTRATION.)

Indomethacin: In a study in 36 patients with mild to moderate hypertension where the antihypertensive effects of ZESTRIL alone were compared to ZESTRIL given concomitantly with indomethacin, the use of indomethacin was associated with a reduced effect, although the difference between the two regimens was not significant.

Other Agents: ZESTRIL has been used concomitantly with nitrates and/or digoxin without evidence of clinically significant adverse interactions. No clinically important pharmacokinetic interactions occurred when ZESTRIL was used concomitantly with propranolol or hydrochlorothiazide. The presence of food in the stomach does not alter the bioavailability of ZESTRIL.

Agents Increasing Serum Potassium: ZESTRIL attenuates potassium loss caused by thiazide-type diuretics. Use of ZESTRIL with potassium-sparing diuretics (eg, spironolactone, triamterene or amiloride), potassium supplements, or potassium-containing salt substitutes may lead to significant increases in serum potassium. Therefore, if concomitant use of these agents is indicated because of demonstrated hypokalemia, they should be used with caution and with frequent monitoring of serum potassium.

Lithium: Lithium toxicity has been reported in patients receiving lithium with drugs which cause elimination of sodium, including ACE inhibitors. Lithium toxicity was usually reversible upon discontinuation of both drugs. It is recommended that serum lithium levels be monitored frequently if ZESTRIL is administered concomitantly with lithium.

Carcinogenesis, Mutagenesis, Impairment of Fertility: There was no evidence of a tumorigenic effect when lisinopril was administered for 105 weeks to male and female rats at doses up to 90 mg/kg/day (about 56 times* the maximum recommended daily human dose) or when lisinopril was administered for 92 weeks to (male and female) mice at doses up to 135 mg/kg/day (about 84 times* the maximum recommended daily human dose).

*Based on patient weight of 50 kg.

Lisinopril was not mutagenic in the Ames microbial mutagen test with or without metabolic activation. It was also negative in a forward mutation assay using Chinese hamster lung cells. Lisinopril did not produce single strand DNA breaks in an in vitro alkaline elution rat hepatocyte assay. In addition, lisinopril did not produce increases in chromosomal aberrations in an in vitro test in Chinese hamster ovary cells or in an in vivo study in mouse bone marrow.

There were no adverse effects on reproductive performance in male and female rats treated with up to 300 mg/kg/day of lisinopril.

Pregnancy: Pregnancy Category D. See WARNINGS, Fetal/Neonatal Morbidity and Mortality.

Nursing Mothers: Milk of lactating rats contains radioactivity following administration of ^{14}C lisinopril. 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 ZESTRIL is given to a nursing mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: ZESTRIL has been found to be generally well tolerated in controlled clinical trials involving 2003 patients and subjects.

The most frequent clinical adverse experiences in controlled trials with ZESTRIL were dizziness (6.3%), headache (5.3%), fatigue (3.3%), diarrhea (3.2%), upper respiratory symptoms (3.0%), and cough (2.9%), all of which were more frequent than in placebo-treated patients. For the most part, adverse experiences were mild and transient in nature. Discontinuation of therapy was required in 6.0% of patients. In clinical trials, the overall frequency of adverse experiences could not be related to total daily dosage within the recommended therapeutic dosage range.

For adverse experiences which occurred in more than 1% of patients and subjects treated with ZESTRIL or ZESTRIL plus hydrochlorothiazide in controlled clinical trials, comparative incidence data are listed in the table below.

Percent of Patients in Controlled Studies

	ZESTRIL (n=2003†) Incidence (discontinuation)	ZESTRIL/ Hydrochlorothiazide (n=644) Incidence (discontinuation)	Placebo (n=207) Incidence
Dizziness	6.3 (0.6)	9.0 (0.9)	1.9
Headache	5.3 (0.2)	4.3 (0.5)	1.9
Fatigue	3.3 (0.2)	3.9 (0.5)	1.0
Diarrhea	3.2 (0.3)	2.6 (0.3)	2.4
Upper Respiratory Symptoms	3.0 (0.0)	4.5 (0.0)	0.0
Cough	2.9 (0.4)	4.5 (0.8)	1.0
Nausea	2.3 (0.3)	2.5 (0.2)	2.4
Hypotension	1.8 (0.8)	1.6 (0.5)	0.5
Rash	1.5 (0.4)	1.6 (0.2)	0.5
Orthostatic Effects	1.4 (0.0)	3.4 (0.2)	1.0
Asthenia	1.3 (0.4)	2.0 (0.2)	1.0
Chest Pain	1.3 (0.1)	1.2 (0.2)	1.4
Vomiting	1.3 (0.2)	1.4 (0.0)	0.5
Dyspnea	1.1 (0.0)	0.5 (0.2)	1.4
Dyspepsia	1.0 (0.0)	1.9 (0.0)	0.0
Paresthesia	0.8 (0.0)	2.0 (0.2)	0.0
Impotence	0.7 (0.2)	1.6 (0.3)	0.0
Muscle Cramps	0.6 (0.0)	2.8 (0.6)	0.5
Back Pain	0.5 (0.0)	1.1 (0.0)	1.4
Nasal Congestion	0.3 (0.0)	1.2 (0.0)	0.0
Decreased Libido	0.2 (0.1)	1.2 (0.0)	0.0
Vertigo	0.1 (0.0)	1.1 (0.2)	0.0

†Includes 420 patients treated for congestive heart failure who were receiving concomitant digitalis and/or diuretic therapy.

Clinical adverse experiences occurring in 0.3% to 1.0% of patients in the controlled trials and rarer, serious, possibly drug related events reported in uncontrolled studies or marketing experience are listed below and, within each category, are in order of decreasing severity.

BODY AS A WHOLE: Chest discomfort, fever, flushing, malaise.

CARDIOVASCULAR: Myocardial infarction or cerebrovascular accident, possibly secondary to excessive hypotension in high risk patients (see WARNINGS, Hypotension); angina pectoris, orthostatic hypotension, rhythm disturbances, tachycardia, peripheral edema, vasculitis, palpitation.

DIGESTIVE: Pancreatitis, hepatitis (hepatocellular or cholestatic jaundice), abdominal pain, anorexia, constipation, flatulence, dry mouth.

METABOLISM: Gout

MUSCULOSKELETAL: Joint pain, shoulder pain.

NERVOUS SYSTEM/PSYCHIATRIC: Depression, somnolence, insomnia, stroke, nervousness, confusion.

RESPIRATORY SYSTEM: Bronchitis, sinusitis, pharyngeal pain.

SKIN: Urticaria, pruritus, diaphoresis.

SPECIAL SENSES: Blurred vision.

UROGENITAL: Oliguria, progressive azotemia, acute renal failure, urinary tract infection.

A symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia and fever.

ANGIOEDEMA: Angioedema has been reported in patients receiving ZESTRIL (0.1%). Angioedema associated with laryngeal edema may be fatal. If angioedema of the face, extremities, lips, tongue, glottis and/or larynx occurs, treatment with ZESTRIL should be discontinued and appropriate therapy instituted immediately. (See WARNINGS.)

HYPOTENSION: In hypertensive patients, hypotension occurred in 1.2% and syncope occurred in 0.1% of patients. Hypotension or syncope was a cause of discontinuation of therapy in 0.5% of hypertensive patients. (See WARNINGS.)

In patients with congestive heart failure, hypotension occurred in 5.0% and syncope occurred in 1.0% of patients. These adverse experiences were causes for discontinuation of therapy in 1.3% of these patients.

Fetal/Neonatal Morbidity and Mortality: In infants exposed in utero to ACE inhibitors the following adverse experiences have been reported: Fetal and neonatal death, renal failure,hypoplastic lung development, hypotension, hyperkalemia, skull hypoplasia, limb contractures, craniofacial deformities, intrauterine growth retardation, prematurity and patent ductus arteriosus. (See WARNINGS, Fetal/Neonatal Morbidity and Mortality.)

Clinical Laboratory Test Findings: Serum Electrolytes: Hyperkalemia. (See PRECAUTIONS.)

Creatinine, Blood Urea Nitrogen: Minor increases in blood urea nitrogen and serum creatinine, reversible upon discontinuation of therapy, were observed in about 2.0% of patients with essential hypertension treated with ZESTRIL alone. Increases were more common in patients receiving concomitant diuretics and in patients with renal artery stenosis. (See PRECAUTIONS.) Reversible minor increases in blood urea nitrogen and serum creatinine were observed in approximately 9.1% of patients with congestive heart failure on concomitant diuretic therapy. Frequently, these abnormalities resolved when the dosage of the diuretic was decreased.

Hemoglobin and Hematocrit: Small decreases in hemoglobin and hematocrit (mean decreases of approximately 0.4 g% and 1.3 vol%, respectively) occurred frequently in patients treated with ZESTRIL but were rarely of clinical importance in patients without some other cause of anemia. In clinical trials, less than 0.1% of patients discontinued therapy due to anemia.

Other (Causal Relationship Unknown): Rarely, elevations of liver enzymes and/or serum bilirubin have occurred. In marketing experience, rare cases of neutropenia and bone marrow depression have been reported.

Overall, 2.0% of patients discontinued therapy due to laboratory adverse experiences, principally elevations in blood urea nitrogen (0.6%), serum creatinine (0.5%) and serum potassium (0.4%).

DOSAGE AND ADMINISTRATION: Initial Therapy: In patients with uncomplicated essential hypertension not on diuretic therapy, the recommended initial dose is 10 mg once a day. Dosage should be adjusted according to blood pressure response. The usual dosage range is 20-40 mg per day administered in a single daily dose. The antihypertensive effect may diminish toward the end of the dosing interval regardless of the administered dose, but most commonly with a dose of 10 mg daily. This can be evaluated by measuring blood pressure just prior to dosing to determine whether satisfactory control is being maintained for 24 hours. If it is not, an increase in dose should be considered. Doses up to 80 mg have been used but do not appear to give greater effect. If blood pressure is not controlled with ZESTRIL alone, a low dose of a diuretic may be added. Hydrochlorothiazide, 12.5 mg has been shown to provide an additive effect. After the addition of a diuretic, it may be possible to reduce the dose of ZESTRIL.

Diuretic Treated Patients: In hypertensive patients who are currently being treated with a diuretic, symptomatic hypotension may occur occasionally following the initial dose of ZESTRIL. The diuretic should be discontinued, if possible, for two to three days before beginning therapy with ZESTRIL to reduce the likelihood of hypotension. (See WARNINGS.) The dosage of ZESTRIL should be adjusted according to blood pressure response. If the patient's blood pressure is not controlled with ZESTRIL alone, diuretic therapy may be resumed as described above.

If the diuretic cannot be discontinued, an initial dose of 5 mg should be used under medical supervision for at least two hours and until blood pressure has stabilized for at least an additional hour. (See WARNINGS and PRECAUTIONS, Drug Interactions.)

Concomitant administration of ZESTRIL with potassium supplements, potassium salt substitutes, or potassium-sparing diuretics may lead to increases of serum potassium. (See PRECAUTIONS.)

Use in Elderly: In general, blood pressure response and adverse experiences were similar in younger and older patients given similar doses of ZESTRIL. Pharmacokinetic studies, however, indicate that maximum blood levels and area under the plasma concentration time curve (AUC) are doubled in older patients so that dosage adjustments should be made with particular caution.

Dosage Adjustment in Renal Impairment: The usual dose of ZESTRIL (10 mg) is recommended for patients with creatinine clearance > 30 mL/min (serum creatinine of up to approximately 3 mg/dL). For patients with creatinine clearance ≥ 10 mL/min ≤ 30 mL/min (serum creatinine ≥ 3 mg/dL), the first dose is 5 mg once daily. For patients with creatinine clearance < 10 mL/min (usually on hemodialysis) the recommended initial dose is 2.5 mg. The dosage may be titrated upward until blood pressure is controlled or to a maximum of 40 mg daily.

Renal Status	Creatinine Clearance mL/min	Initial Dose mg/day
Normal Renal Function to Mild Impairment	>30	10
Moderate to Severe Impairment	≥10 ≤30	5
Dialysis Patients	<10	2.5‡

‡Dosage or dosing interval should be adjusted depending on the blood pressure response.

HOW SUPPLIED

5 mg Tablets (NDC 0038-0130) pink, round, biconvex, uncoated, scored tablets, identified "ZESTRIL 5" debossed on one side, and "130" debossed and scored on the other side are supplied in bottles of 100 tablets and unit dose packages of 100 tablets.

10 mg Tablets (NDC 0038-0131) pink, round, biconvex, uncoated tablets identified "ZESTRIL 10" debossed on one side, and "131" debossed on the other side are supplied in bottles of 100 tablets and unit dose packages of 100 tablets.

20 mg Tablets (NDC 0038-0132) red, round, biconvex, uncoated tablets identified "ZESTRIL 20" debossed on one side, and "132" debossed on the other side are supplied in bottles of 100 tablets and unit dose packages of 100 tablets.

40 mg Tablets (NDC 0038-0134) yellow, round, biconvex, uncoated tablets identified "ZESTRIL 40" debossed on one side, and "134" debossed on the other side are supplied in bottles of 100 tablets and unit dose packages of 100 tablets.

Store at room temperature. Protect from moisture, freezing and excessive heat. Dispense in a tight container.

STUART PHARMACEUTICALS
A business unit of ICI Americas Inc.
Wilmington, Delaware 19897 USA

Rev V 01/91

Axsain® Is Now **Zostrix®-HP**

Axsain®

(Capsaicin 0.075%) Cream

The topically active analgesic
for peripheral neuropathies

Effective relief for the burning, throbbing, lancinating pain of diabetic neuropathy

Axsain® Is Now **Zostrix®-HP**

Axsain®

(Capsaicin 0.075%) Cream

Unique topical therapy relieves pain of diabetic neuropathy

- **Topical, with no known systemic effects or drug interactions**
- **Pain selective; does not affect more discriminatory senses such as touch, pressure or vibration**
- **Patients applying Axsain three to four times daily report noticeable pain relief within two to four weeks**

Effective relief is achieved through proper patient use

Axsain should be rubbed into the skin in amounts sufficient to cover the area without resulting in a caked residue. If residue of dried material is left on the skin it may become airborne, which can cause coughing, sneezing and/or tearing.

A transient burning sensation and reddening of the skin may occur over the first several days of use. Application fewer than three times a day may not provide optimum pain relief and may cause the burning sensation to persist.

Illustrated, easy-to-read patient instruction booklets are included in every Axsain package.

Description: Axsain contains capsaicin 0.075% in an emollient cream base. Capsaicin is trans-8-methyl-N-vanillyl-6-nonenamide, a white crystalline powder with a molecular weight of 305.4. It is practically insoluble in water but very soluble in alcohol, ether and chloroform.

Active Ingredient: Capsaicin 0.075%

Inactive Ingredients: Benzyl Alcohol, Cetyl Alcohol, Glyceryl Monostearate, Isopropyl Myristate, Polyoxyethylene Stearate Blend, Purified Water, Sorbitol Solution, White Petrolatum

Actions and Indications: Current evidence suggests that Axsain works by its action on pain fibers and on a pain transmitting compound called substance P. The capsaicin in Axsain causes substance P to leave the nerve endings. With a lower amount of substance P in the nerve endings, pain impulses cannot be transmitted to the brain. Axsain is indicated for relief of neuralgias (pain from nerves near the surface of the skin) such as painful diabetic neuropathy and postsurgical pain.

Warnings: Avoid contact with eyes. Do not apply to wounds or damaged skin. Do not bandage tightly. Avoid inhaling airborne material from dried residue which can cause coughing, sneezing and/or tearing. If painful condition worsens or does not improve after 28 days, discontinue use of this product and consult your physician. Keep this and all drugs out of the reach of children.

Directions: Adults and children 2 years of age and older: Apply to affected area 3 to 4 times daily. A transient burning sensation related to the action of the product may occur over the first several days of use. Application schedules less than 3 times a day may not provide optimum pain relief and the burning sensation may persist. Wash hands immediately after application, avoiding areas where drug is applied.

How Supplied: 1.0 oz. tubes (NDC 57284-501-30) 2.0 oz. tubes (NDC 57284-501-60) U.S. Patent Nos. 4,486,450 and 4,536,404

GenDerm Corporation
Lincolnshire, IL 60069

Marketed by GENDERM® knoll BASF Group

DRM-171D
Printed in U.S.A.

JUNE 20-23, 1992

PRELIMINARY PROGRAM

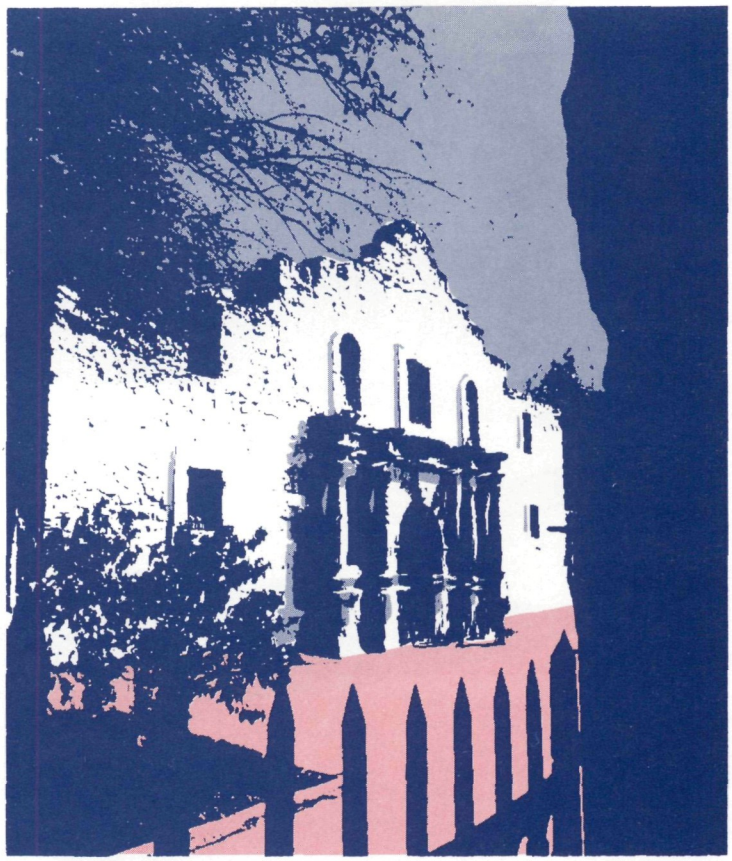
SAN ANTONIO

52nd ANNUAL MEETING & SCIENTIFIC SESSIONS

American Diabetes Association

SAN ANTONIO

San Antonio is Texas' most popular visitor destination. The city's winding River Walk, anchored by hotels and the convention center, is visitor friendly. Strung with cafes, clubs, shops and stretches of subtropical park, and enlivened with colorful river traffic and sidewalk performers, the River Walk gives downtown a true second dimension. Mixing historic and architectural sites with family entertainment attractions, it serves up a spicy multicultural brew in a Spanish, German, Southern, Western, and Mexican atmosphere.



Scientific Sessions Meeting Committee—1991-1992

Samuel W. Cushman, PhD, Chair
Debra Haire-Joshu, RN, PhD, Vice Chair
Alan Chait, MD
Phyllis A. Crapo, RD
Ruth Farkas-Hirsch, MS, RN, CDE
Maureen I. Harris, PhD, MPH
Steven J. Jacobs, MD
Abbas E. Kitabchi, PhD, MD
Noel K. Maclaren, MD
David G. Marrero, PhD
M. Alan Permutt, MD
Aaron I. Vinik, MD, PhD

Professional Section Council Chairs—1991-1992

Council on Behavioral Medicine and Psychology
Tim Wysocki, PhD

Council on Clinical Endocrinology, Diabetes, & Metabolism (new Council)
To Be Elected

Council on Complications
Michael A. Brownlee, MD

Council on Diabetes in Pregnancy
John W. Hare, MD

Council on Diabetes in Youth
Morey Haymond, MD

Council on Education
Deborah Hinnen, RN, MN, CDE

Council on Epidemiology & Statistics
Ronald Klein, MD, MPH

Council on Exercise
Stephen H. Schneider, MD

Council on Foot Care
Phala Helm, MD

Council on Health Care Delivery and Public Health
Gayle Reiber, PhD

Council on Molecular, Cellular, & Biochemical Aspects of Diabetes (new Council)
To Be Elected

Council on Nutritional Science and Metabolism
Clarie Hollenbeck, PhD

WHO SHOULD ATTEND?

The American Diabetes Association and the 1992 Scientific Sessions Meeting Committee invite the participation of all professionals involved in diabetes research and in the delivery of diabetes care and services. Physicians, scientists, nurses, dietitians, administrators, and other health care professionals will benefit from the comprehensive programming and stimulating atmosphere. From the structured sessions to the exposition, participants will be challenged to update and review their knowledge in diabetes practice and research.

SAN ANTONIO
52nd ANNUAL MEETING
&
SCIENTIFIC SESSIONS

If the growing need for the latest and most exciting information in diabetes research and clinical care affects you, the **52nd Annual Scientific Sessions** will be the year's premier opportunity for your professional development. Mark your calendar now for **June 20-23, 1992** in **SAN ANTONIO.**

LOCATION AND DATES

The Scientific Sessions and Exposition will be held in the San Antonio Convention Center.

The meeting opens 8:30 am Saturday, June 20 with symposia organized by ADA's Professional Section Councils and concludes by 4:00 pm on Tuesday, June 23. The Awards Banquet will be held at the Marriott Rivercenter Hotel on Saturday.

ADVANCED REGISTRATION

Take advantage of registration discounts and register early! Please use the **Advanced Registration Form included in this program. Advanced Registration must be postmarked and all fees paid by May 15, 1992.**

If you cannot pre-register by that date, you must register on-site in San Antonio and pay the on-site registration fees.

CONTINUING EDUCATION

The American Diabetes Association (ADA) is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians. As such, ADA certifies that this continuing medical education activity meets the criteria for 27 credit hours in Category 1 for the Physician's Recognition Award of the American Medical Association.

ADA is accredited by the Virginia Nurses Association, which is accredited by the Eastern Regional Accrediting Committee of the American Nurses' Association, to provide continuing education units to nurses. As such, the ADA certifies that this continuing education program has been approved for 32 contact hours.

ADA also has applied to the American Dietetic Association for accreditation.

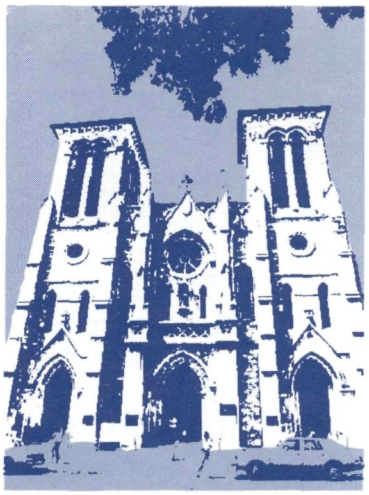
NEW EXPANDED FORMAT

This year the number of program sessions has been increased by 75%! Expanded programming for clinical practice has been added to the dozens of lectures and hundreds of poster presentations on basic and clinical diabetes research.

PROGRAM SCHEDULE

Preliminary Program
Scientific Sessions

Saturday, June 20, 1992



Professional Section Council Symposia

Morning

Macro and Microvascular Disease Complicating Pregnancy

Coping: An Experience with Diabetes Adherence and Health and Status in Diabetes: A Behavioral Challenge

Therapeutic Strategies for Managing Charcot Foot

Diabetic Renal Disease: Epidemiology, Clinical Advances, and Cost Considerations

Weight Management Issues: Directions for the Next Decade

Afternoon

Diabetes Complications: A Challenge for Behavioral Medicine

New Developments in the Pharmacology of Diabetic Complications

Cardiovascular Complications in Diabetes

Role of Exercise and Physical Training in the Primary Prevention of Type II Diabetes

Recent Public Policy Initiatives and the Practice of Clinical Endocrinology

Transgenic Animals and Targeted Gene Knockout as Tools for Diabetes Research

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EXHIBIT HALL OPEN 2:00 PM - 4:30 PM

Preliminary Program

Sunday, June 21, 1992

Morning

Concurrent Symposia

Lifestyle Risk Factors as Complications of Diabetes
Gestational Diabetes Update
Cell Biology of Insulin Production & Secretion

Exhibit Hall Open

Poster Session

Afternoon

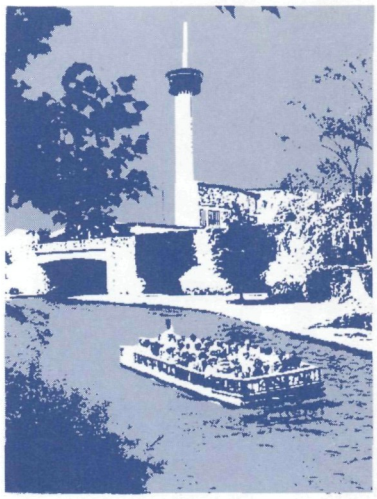
Concurrent Symposia

Lipids and Obesity
Glucose Signalling in the Beta Cell
Insulin Regulation of Gene Expression
Quality Assurance of Diabetes Treatment

President's Address

Banting Lecture

President's Poster Session



Monday, June 22, 1992

Morning

Concurrent Symposia

Variations of Diabetes in Minorities
Signal Relays
Role of Glucose & Hyperglycemia in the Complications of Diabetes
Clinical Implications of Exercise Therapy

Exhibit Hall Open

Poster Session

Afternoon

Concurrent Symposia

New Technologies in Diabetes Therapy
New Approaches to Measuring in vivo *Metabolism*
Research Advances in the Mechanisms Regulating Glucose Transport
Diet Therapy in Diabetes

Lilly Lecture

Tuesday, June 23, 1992

Morning

Symposium

Predicting and Preventing IDDM

Exhibit Hall Open

Poster Session

Afternoon

Concurrent Symposia

Therapeutic Endpoints in Diabetes: How do we Measure Success?
Search for the Diabetes Gene(s)
Insulin Degradation

ADVANCED REGISTRATION INSTRUCTIONS

ADVANCED REGISTRATION

Final Advanced Registration Deadline: May 15, 1992

Mail your completed form, with payment to:

American Diabetes Association
Meeting Registrar
1660 Duke Street
Alexandria, VA 22314

(Checks payable to the American Diabetes Association in US funds only, drawn on a US bank)

Please read the following instructions carefully.
(one registrant per form; make duplicates if necessary)

1. **Personal Data**—Please type or print all information clearly. Important: include a phone number where you can be reached 8:30am - 5:00pm EST.

2. **Registration Fees**—Please circle the appropriate registration category and fee. If daily registration is selected, please indicate which day.

3. **Awards Banquet**—If you are purchasing banquet tickets, please indicate either fish or beef, and the number of tickets for each type of meal being purchased.

4. **Payment**—Registration Form MUST be accompanied by payment to be processed. Payment may be made by check, payable to the American Diabetes Association (drawn on a U.S. bank and in U.S. funds) or by Mastercard, Visa or American Express credit cards.

- ADA will not honor overseas wire transfers, purchase orders, or vouchers as a substitute for payment.
- If your institution is paying your registration fee, please arrange for payment to be made before the registration deadlines. Please ensure that the check is appropriately identified with your name.

5. **Refund Policy**—Refund requests must be submitted in writing and postmarked by May 22, 1992. Requests postmarked before March 30, 1992 will receive a full refund less a $25.00 processing fee. Refund requests postmarked between March 31, 1992 and May 22, 1992 will receive a refund less 50%. Refund requests postmarked after May 22, 1992 will not be honored.

6. **Confirmation**—Upon receipt of your registration form, a confirmation notice will be mailed to you with instructions for badge and conference material pick-up.

7. **On-Site Registration**—If you have not postmarked your registration by May 15, plan to register on-site at the San Antonio Convention Center.

GENERAL INFORMATION

REGISTRATION FEES

	Postmarked on or Before March 15	Postmarked Between March 16 and May 15	Postmarked After May 15 or On-Site
ADA Member	$160	$175	$190
Non-Member	$270	$285	$300
Student/Resident/Fellow	$ 75	$ 90	$105

ON-SITE REGISTRATION

Registration at the San Antonio Convention Center is scheduled for the days and hours listed below:

Friday, June 19	6:00 pm - 8:30 pm
Saturday, June 20	7:00 am - 6:00 pm
Sunday, June 21	7:00 am - 5:00 pm
Monday, June 22	7:00 am - 4:00 pm
Tuesday, June 23	7:00 am - 12:00 noon

LODGING AND HOTEL RESERVATIONS

A Housing Form is included with this Advanced Preliminary Program. To ensure assignment to the hotel of your choice, please complete the application for hotel accommodations and mail to the address on the Housing Form. Sleeping room blocks have been reserved with negotiated discount room rates only at the hotels listed on the Housing Form. Mailing this form to the ADA National Center, or directly to the hotel, will delay your reservation request. Room and hotel assignments are done on a first come—first served basis.

HOTEL CANCELLATIONS

All requests for changes or cancellations must be made in writing to the ADA Housing Bureau, by **May 18, 1992.** After May 18, contact hotel directly. (See Housing Form for address.) All hotels require a minimum of 72 hours cancellation notice to refund your deposit.

GROUND TRANSPORTATION

Super Shuttle is the local ground transportation service from the San Antonio International Airport to the downtown hotels. Cost of a one way ticket is $8.00. Super Shuttle's phone number is (512) 344-7433. The average taxi fare is $15.00.

AIR TRAVEL DISCOUNTS

Delta and Continental Airlines are the official co-carriers for the 52nd Annual Scientific Sessions. Negotiated discounts have been arranged to ensure the best and most economical service for your travel requirements. Arrangements can be made directly with ADA's travel service at 1-800-42-TRAVL.

ADVANCED RESERVATION

PARTICIPATING CONVENTION HOTELS AND RATES

Alphabetical list corresponds to map:

Hotel Name	Hotel Code
1. **Crocket Hotel** 320 Bonham $79 single or double	**CRO**
2. **Hilton Palacio del Rio Hotel** 200 South Alamo $118 single $128 double	**HPR**
3. **Hyatt Regency Hotel** 123 Losoya $116 single $136 double	**HYR**
4. **La Mansion del Rio Hotel** 112 College Street $110 single $125 double	**LMR**
5. **La Quinta—Convention Center** 1001 East Commerce $80 single or double	**LCQ**
6. **Marriott Rivercenter Hotel** 101 Bowie $126 single $141 double	**MRC**
7. **Marriott Riverwalk Hotel** 711 East River Walk $116 single $136 double	**SAM**
8. **Menger Hotel** 204 Alamo Plaza $80 single $90 double	**MEN**
9. **Plaza San Antonio Hotel** 555 South Alamo $98 single $118 double	**PLZ**
10. **St. Anthony Hotel** 300 East Travis $80 single $90 double	**SAI**

American Diabetes Association®

ADA 52ND ANNUAL SCIENTIFIC SESSIONS, JUNE 20-23, 1992, SAN ANTONIO, TEXAS

PREREGISTRATION FORM

SAN ANTONIO

Please register only one person per form. This form can be copied for additional registrants. Please type or print all information clearly.

SECTION A: PERSONAL DATA

Academic degrees or licensure: ☐ MD ☐ DO ☐ PhD ☐ RN ☐ RD ☐ RPh Other ____ (please indicate)

First Name, M.I., Last Name

Title

Professional Affiliation/Institution

Business Address

City State Postal Code

Country Fax with Area Code Telephone with Area Code

Special Needs - individuals with special needs (mobility, access, etc.) should indicate specific needs in a letter attached to your registration form.

1. **Specialty Area (check one)**

- ☐ a. Adult Endocrinology
- ☐ b. Epidemiology
- ☐ c. Family Practice
- ☐ d. Geriatrics
- ☐ e. Internal Medicine
- ☐ f. Nursing
- ☐ g. Nutrition
- ☐ h. Ophthalmology
- ☐ i. Obstetrics/Gynecology
- ☐ j. Pediatrics
- ☐ k. Pediatric Endocrinology
- ☐ l. Pharmacy
- ☐ m. Podiatry
- ☐ n. Psychology
- ☐ o. Public Health
- ☐ p. Research
- ☐ q. Other _____

2. **Type of Practice (check one)**

- ☐ a. Clinic
- ☐ b. Corporate
- ☐ c. Hospital
- ☐ d. Private Practice
- ☐ e. Public Health
- ☐ f. Research
- ☐ g. Student
- ☐ h. Academic
- ☐ i. HMO
- ☐ j. Government/Military
- ☐ k. Other _____

SECTION B. REGISTRATION FEES (please circle the appropriate fee category)

	Received Before March 15	Between March 16 and May 15	After May 15 or On-Site
ADA Member	$ 160	$ 175	$ 190
Non-Member	270	285	300
Student/Resident/Fellow	75	90	105

One Day Registration Fee 125

Student/Resident/Fellow 60

Day Attending _____

TOTAL PAYMENT FOR SECTION B: $ _____

NON-MEMBER: If you join **ADA NOW,** you may register at the ADA member rates. See attached membership application for ADA membership categories, benefits, and dues. Return your completed application form with registration. Your membership check must be separate from registration fees.

REFUND POLICY:

All refund requests must be submitted in writing and postmarked by May 22, 1992. Refund requests postmarked before March 30, 1992 will receive a full refund LESS a 25% processing fee. Refund requests postmarked between March 31, 1992 and May 22, 1992 wil receive a registration refund LESS 50%. Refund requests postmarked after May 22, 1992 will not be honored.

For ADA use only:

Check # _____ B/P Charge _____ AMEX/MC/VISA

_____ Amount Received _____ Date Received

SECTION C: AWARDS BANQUET

Saturday, June 20, 1992

Banquet ticket(s) $60.00 each: indicate number of each type of ticket being purchased

_____ # of fish _____ # of beef

TOTAL PAYMENT FOR SECTION C: $ _____

SECTION D: PAYMENT OF FEES

Registrants must pay by check, money order, or American Express, Mastercard or Visa credit cards. Checks and money orders must be made payable to the AMERICAN DIABETES ASSOCIATION in U.S. dollars drawn on a U.S. bank. Your name and address should be typed or printed clearly on your check.

TOTAL PAYMENT SECTION B $ _____

TOTAL PAYMENT SECTION C $ _____

TOTAL PAYMENT FEE $ _____

METHOD OF PAYMENT:

☐ Check ☐ Money Order ☐ American Express ☐ Visa ☐ MasterCard

Card issued in the name of

(please print) _____

Card number: _____

Expiration Date: _____

I authorize the American Diabetes Association to charge the total fee indicated on this form to my credit card: _____ Signature

SECTION E: MAILING INFORMATION

Please complete and return this form to:

AMERICAN DIABETES ASSOCIATION MEETING REGISTRAR

1660 DUKE STREET ALEXANDRIA, VA 22314

For questions, call ..... 1-800-ADA-DISC ext. 330

..... 703-549-1500 ext. 330

MAIL TO: ADA HOUSING
P.O. BOX 2277
SAN ANTONIO, TX 78298

American Diabetes Association®

RESERVATION CUTOFF DATE: MAY 15, 1992

Official Housing Request Form June 20-23, 1992 Scientific Session

INSTRUCTIONS:

- Telephone or fax request not accepted.
- Please print or type all items to ensure accuracy and rapid computer processing.
- Only one reservation per form is allowed. Please photocopy this form if additional forms are needed.
- Acknowledgement(s) of receipt of Housing Form will be sent only to the individual at the address given below.
- Hotel will send actual confirmation notice to the person listed below. (Refer to Prepayment Requirement below.)

(LAST NAME) (FIRST)

(PROFESSIONAL AFFILIATION/INSTITUTION)

(STREET ADDRESS OR P.O. BOX NUMBER)

(CITY) (STATE) (ZIP-USA)

(COUNTRY) (AREA CODE) (OFFICE NUMBER)

INSTRUCTIONS: Select SIX Hotels/Motels of your choice. Request will not be processed without SIX choices. USE CODES ONLY— DO NOT USE NUMBERS—REFER TO MAP FOR HOTEL CODES.

First Choice Second Choice Third Choice

Fourth Choice Fifth Choice Sixth Choice

Prepayment Requirement:

Please enclose a U.S. check drawn on a U.S. bank and made payable to ADA Housing. Payment can also be made with an American Express, MasterCard, or Visa Card. Please provide card number and expiration date. To receive a full refund, cancellation must be received by the hotel no later that 72 hours prior to the arrival date (not including the arrival date).

Print name as it appears on card Type of card AE, MC, Visa

Credit card number Expiration date

_____ I authorize use of my card for this purpose.
Signature

* **Special Note:** Rooms are assigned on "First Come/First Served" basis AND room availability for your arrival/departure. If none of the choices listed is available, another facility will be assigned. Rooms required two or more days post or pre convention are not always available through the housing bureau. If not available, the Housing Bureau will advise you to call the hotel directly for additional nights (not always available at convention rate).

DO NOT DUPLICATE—if sharing a room designate ONE person to submit Housing Request Form.
Occupant(s) print—last name first

1. _____
2. _____
3. _____
4. _____

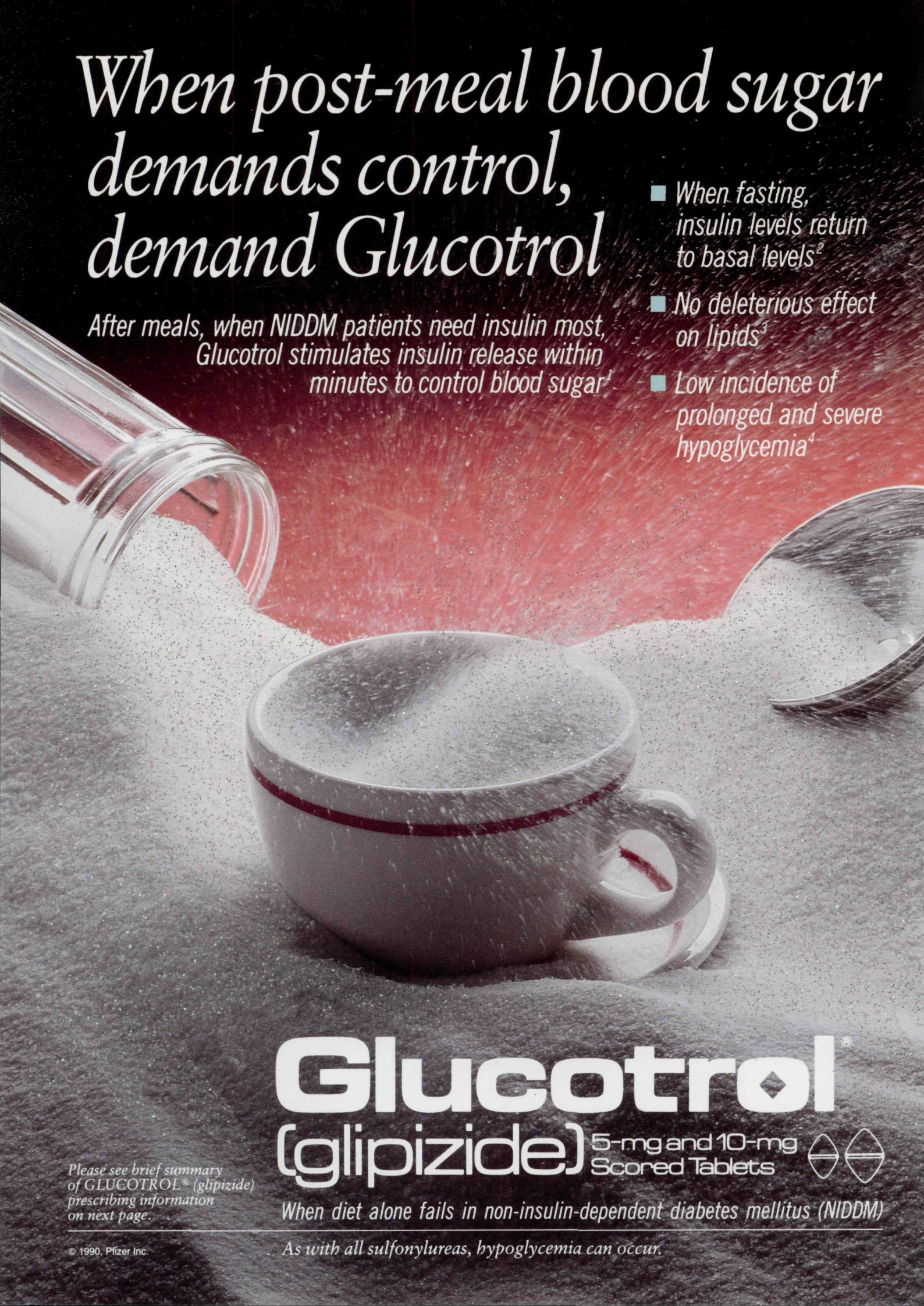
Special Note: Housing form cannot be processed without all information completed.
ARRIVAL DATE _____
ARRIVAL TIME _____ AM/PM (Approximate)
DEPARTURE DATE _____

SELECT TYPE ROOM DESIRED
___Single (1 pers.,1 bed) ___Double (2 pers., 1 bed) ___Triple (3 pers., 1-2 beds) ___Quad (4 pers., 2 beds)
___Dbl/Dbl (2 pers., 2 beds) Other special needs _____

When post-meal blood sugar demands control, demand Glucotrol

After meals, when NIDDM patients need insulin most, Glucotrol stimulates insulin release within minutes to control blood sugar[1]

- When fasting, insulin levels return to basal levels[2]
- No deleterious effect on lipids[3]
- Low incidence of prolonged and severe hypoglycemia[4]



Glucotrol®

(glipizide) 5-mg and 10-mg Scored Tablets

When diet alone fails in non-insulin-dependent diabetes mellitus (NIDDM)

As with all sulfonylureas, hypoglycemia can occur.

Please see brief summary of GLUCOTROL® (glipizide) prescribing information on next page.

Glucotrol®

(glipizide) 5-mg and 10-mg Scored Tablets

References: 1. Peterson CM, Sims RV, Jones RL, et al: Bioavailability of glipizide and its effect on blood glucose and insulin levels in patients with non-insulin-dependent diabetes. *Diabetes Care* 1982;5:497-500. **2.** Goebel R, Leb G: Effects of glyburide and glipizide on levels of immunoreactive insulin and blood sugar, in *Glipizide: A Worldwide Review*. Princeton, NJ, Excerpta Medica, 1984, pp 9-15. **3.** Reaven GM: Effect of glipizide treatment on various aspects of glucose, insulin, and lipid metabolism in patients with noninsulin-dependent diabetes mellitus. *Am J Med* 1983;75(November 30):8-14. **4.** Berger W, Caduff F, Pasquel M, et al: The relative frequency of severe sulfonylurea hypoglycemia in the last 25 years in Switzerland. *Schweiz Med Wochenschr* 1986;116:145-151.

Brief Summary of Prescribing Information

INDICATIONS AND USAGE: GLUCOTROL is indicated as an adjunct to diet for the control of hyperglycemia in patients with non-insulin-dependent diabetes mellitus (NIDDM, type II) after an adequate trial of dietary therapy has proved unsatisfactory.

CONTRAINDICATIONS: GLUCOTROL is contraindicated in patients with known hypersensitivity to the drug or with diabetic ketoacidosis, with or without coma, which should be treated with insulin.

SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY: The administration of oral hypoglycemic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin. This warning is based on the study conducted by the University Group Diabetes Program (UGDP), a long-term prospective clinical trial designed to evaluate the effectiveness of glucose-lowering drugs in preventing or delaying vascular complications in patients with non-insulin-dependent diabetes. The study involved 823 patients who were randomly assigned to one of four treatment groups (*Diabetes*, 19, supp. 2:747-830, 1970). UGDP reported that patients treated for 5 to 8 years with diet plus a fixed dose of tolbutamide (1.5 grams per day) had a rate of cardiovascular mortality approximately 2-1/2 times that of patients treated with diet alone. A significant increase in total mortality was not observed, but the use of tolbutamide was discontinued based on the increase in cardiovascular mortality, thus limiting the opportunity for the study to show an increase in overall mortality. Despite controversy regarding the interpretation of these results, the findings of the UGDP study provide an adequate basis for this warning. The patient should be informed of the potential risks and advantages of GLUCOTROL and of alternative modes of therapy.

Although only one drug in the sulfonylurea class (tolbutamide) was included in this study, it is prudent from a safety standpoint to consider that this warning may also apply to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

PRECAUTIONS: Renal and Hepatic Disease: The metabolism and excretion of GLUCOTROL may be slowed in patients with impaired renal and/or hepatic function. Hypoglycemia may be prolonged in such patients should it occur.

Hypoglycemia: All sulfonylureas are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemia. Renal or hepatic insufficiency may increase the risk of hypoglycemic reactions. Elderly, debilitated or malnourished patients and those with adrenal or pituitary insufficiency are particularly susceptible to the hypoglycemic action of glucose-lowering drugs. Hypoglycemia may be difficult to recognize in the elderly or people taking beta-adrenergic blocking drugs. Hypoglycemia is more likely to occur when caloric intake is deficient, after severe or prolonged exercise, when alcohol is ingested, or when more than one glucose-lowering drug is used.

Loss of Control of Blood Glucose: A loss of control may occur in diabetic patients exposed to stress such as fever, trauma, infection or surgery. It may then be necessary to discontinue GLUCOTROL and administer insulin.

Laboratory Tests: Blood and urine glucose should be monitored periodically. Measurement of glycosylated hemoglobin may be useful.

Information for Patients: Patients should be informed of the potential risks and advantages of GLUCOTROL, of alternative modes of therapy, as well as the importance of adhering to dietary instructions, of a regular exercise program, and of regular testing of urine and/or blood glucose. The risks of hypoglycemia, its symptoms and treatment, and conditions that predispose to its development should be explained to patients and responsible family members. Primary and secondary failure should also be explained.

Drug Interactions: The hypoglycemic action of sulfonylureas may be potentiated by certain drugs including nonsteroidal anti-inflammatory agents and other drugs that are highly protein bound, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, monoamine oxidase inhibitors, and beta-adrenergic blocking agents. *In vitro* studies indicate that GLUCOTROL binds differently than tolbutamide and does not interact with salicylate or dicumarol. However, caution must be exercised in extrapolating these findings to a clinical situation. Certain drugs tend to produce hyperglycemia and may lead to loss of control, including the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid. A potential interaction between oral miconazole and oral hypoglycemic agents leading to severe hypoglycemia has been reported. Whether this interaction also occurs with the intravenous, topical, or vaginal preparations of miconazole is not known.

Carcinogenesis, Mutagenesis, Impairment of Fertility: A 20-month study in rats and an 18-month study in mice at doses up to 75 times the maximum human dose revealed no evidence of drug-related carcinogenicity. Bacterial and *in vivo* mutagenicity tests were uniformly negative. Studies in rats of both sexes at doses up to 75 times the human dose showed no effects on fertility.

Pregnancy: Pregnancy Category C: GLUCOTROL (glipizide) was found to be mildly fetotoxic in rat reproductive studies at all dose levels (5-50 mg/kg). This fetotoxicity has been similarly noted with other sulfonylureas, such as tolbutamide and tolazamide. The effect is perinatal and believed to be directly related to the pharmacologic (hypoglycemic) action of GLUCOTROL. In studies in rats and rabbits no teratogenic effects were found. There are no adequate and well-controlled studies in pregnant women. GLUCOTROL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Because recent information suggests that abnormal blood glucose levels during pregnancy are associated with a higher incidence of congenital abnormalities, many experts recommend that insulin be used during pregnancy to maintain blood glucose levels as close to normal as possible.

Nonteratogenic Effects: Prolonged severe hypoglycemia has been reported in neonates born to mothers who were receiving a sulfonylurea drug at the time of delivery. This has been reported more frequently with the use of agents with prolonged half-lives. GLUCOTROL should be discontinued at least one month before the expected delivery date.

Nursing Mothers: Since some sulfonylurea drugs are known to be excreted in human milk, insulin therapy should be considered if nursing is to be continued.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: In controlled studies, the frequency of serious adverse reactions reported was very low. Of 702 patients, 11.8% reported adverse reactions and in only 1.5% was GLUCOTROL discontinued.

Hypoglycemia: *See PRECAUTIONS and OVERDOSAGE sections.*

Gastrointestinal: Gastrointestinal disturbances, the most common, were reported with the following approximate incidence: nausea and diarrhea, one in 70; constipation and gastralgia, one in 100. They appear to be dose-related and may disappear on division or reduction of dosage. Cholestatic jaundice may occur rarely with sulfonylureas: GLUCOTROL should be discontinued if this occurs.

Dermatologic: Allergic skin reactions including erythema, morbilliform or maculopapular eruptions, urticaria, pruritus, and eczema have been reported in about one in 70 patients. These may be transient and may disappear despite continued use of GLUCOTROL; if skin reactions persist, the drug should be discontinued. Porphyria cutanea tarda and photosensitivity reactions have been reported with sulfonylureas.

Hematologic: Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas.

Metabolic: Hepatic porphyria and disulfiram-like alcohol reactions have been reported with sulfonylureas. Clinical experience to date has shown that GLUCOTROL has an extremely low incidence of disulfiram-like reactions.

Endocrine Reactions: Cases of hyponatremia and the syndrome of inappropriate antidiuretic hormone (SIADH) secretion have been reported with this and other sulfonylureas.

Miscellaneous: Dizziness, drowsiness, and headache have each been reported in about one in fifty patients treated with GLUCOTROL. They are usually transient and seldom require discontinuance of therapy.

OVERDOSAGE: Overdosage of sulfonylureas including GLUCOTROL can produce hypoglycemia. If hypoglycemic coma is diagnosed or suspected, the patient should be given a rapid intravenous injection of concentrated (50%) glucose solution. This should be followed by a continuous infusion of a more dilute (10%) glucose solution at a rate that will maintain the blood glucose at a level above 100 mg/dL. Patients should be closely monitored for a minimum of 24 to 48 hours since hypoglycemia may recur after apparent clinical recovery. Clearance of GLUCOTROL from plasma would be prolonged in persons with liver disease. Because of the extensive protein binding of GLUCOTROL, dialysis is unlikely to be of benefit.

DOSAGE AND ADMINISTRATION: There is no fixed dosage regimen for the management of diabetes mellitus with GLUCOTROL; in general, it should be given approximately 30 minutes before a meal to achieve the greatest reduction in postprandial hyperglycemia.

Initial Dose: The recommended starting dose is 5 mg before breakfast. Geriatric patients or those with liver disease may be started on 2.5 mg. Dosage adjustments should ordinarily be in increments of 2.5-5 mg, as determined by blood glucose response. At least several days should elapse between titration steps.

Maximum Dose: The maximum recommended total daily dose is 40 mg.

Maintenance: Some patients may be effectively controlled on a once-a-day regimen, while others show better response with divided dosing. Total daily doses above 15 mg should ordinarily be divided.

HOW SUPPLIED: GLUCOTROL is available as white, dye-free, scored, diamond-shaped tablets imprinted as follows: 5 mg tablet—Pfizer 411 (NDC 5 mg 0049-4110-66) Bottles of 100; 10 mg tablet—Pfizer 412 (NDC 10 mg 0049-4120-66) Bottles of 100.

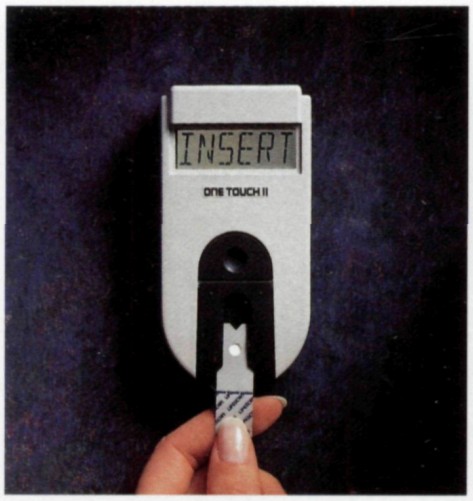
CAUTION: Federal law prohibits dispensing without prescription.

More detailed professional information available on request.

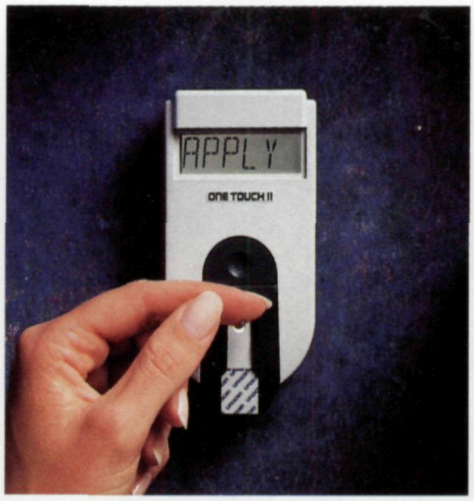
Pfizer

Roerig

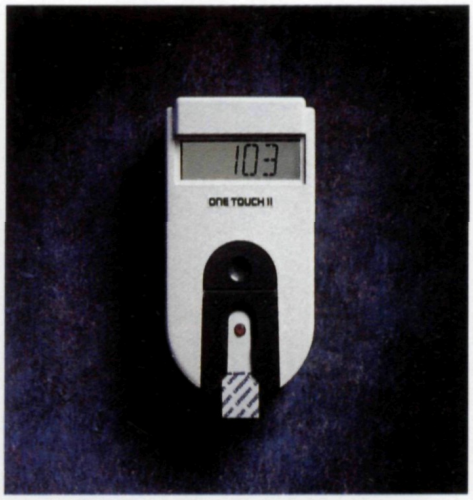
Testing 1-2-3.



Press power, insert strip.



Apply sample. No wiping. No timing.



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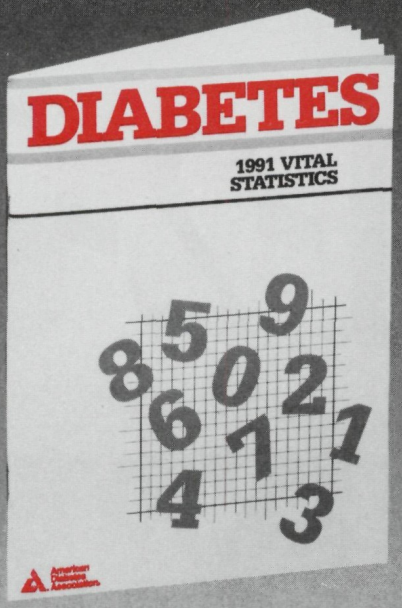

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—Diabetes: 1991 Vital Statistics, pg. 1

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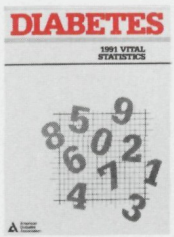

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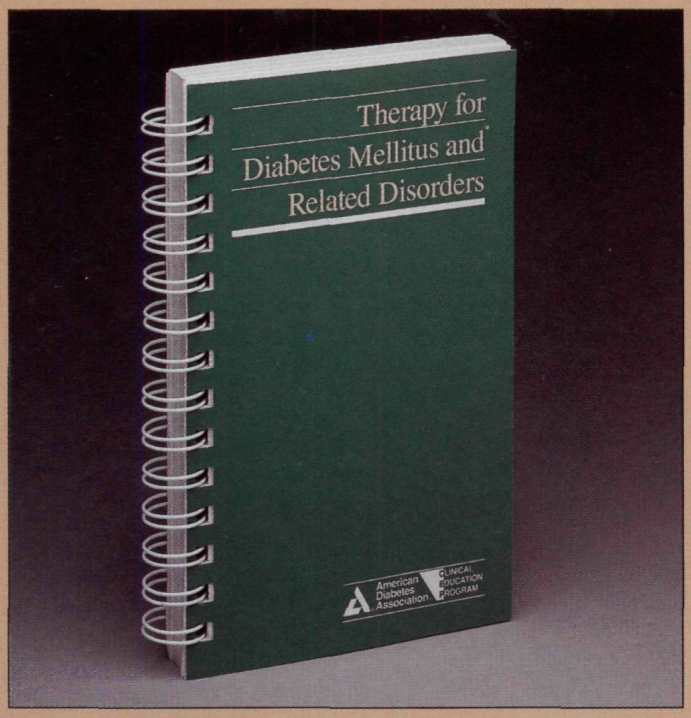

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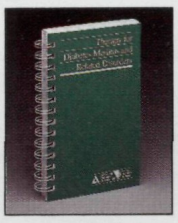

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Fact: GLUCOFILM Test Strips provide the widest hematocrit range available for blood glucose levels from 20-500 mg/dL.

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Fact: GLUCOMETER 3 Diabetes Care System is affordable.

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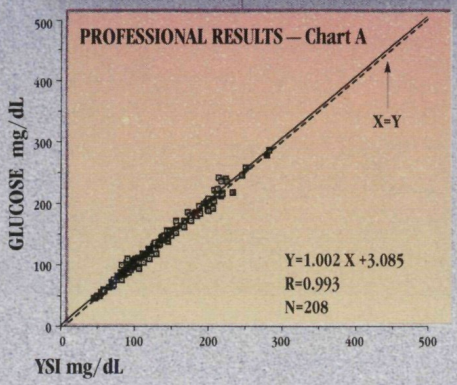

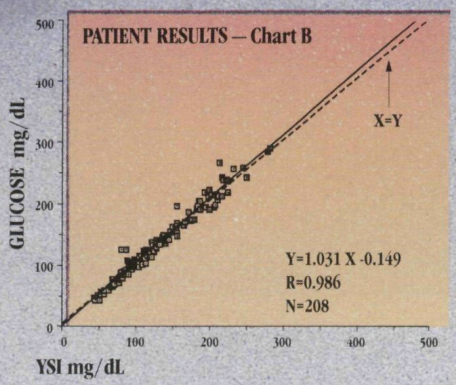

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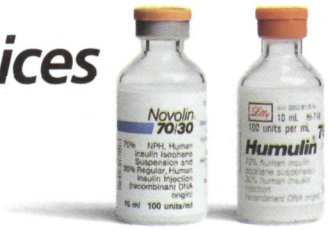
Elkhart, IN 46515

There Are Two Choices Of Human Insulin



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