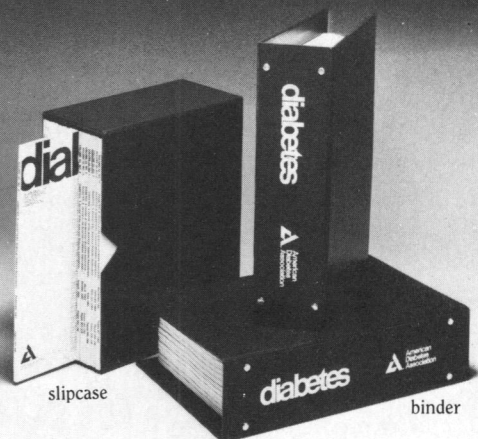


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BRIEF SUMMARY DIABINESE® (chlorpropamide) TABLETS, USP

CONTRAINDICATIONS

DIABINESE is contraindicated in patients with:
1. Known hypersensitivity to the drug
2. Diabetic ketoacidosis, with or without coma. This condition should be treated with insulin.

WARNINGS

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 2½ 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 over-all 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 DIABINESE 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

General

Hypoglycemia: All sulfonylurea drugs are capable of producing severe hypoglycemia. Proper patient selection, dosage, and instructions are important to avoid hypoglycemic episodes. Renal or hepatic insufficiency may cause elevated blood levels of DIABINESE and the latter may also diminish gluconeogenic capacity, both of which increase the risk of serious 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, and in people who are 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.

Because of the long half-life of chlorpropamide, patients who become hypoglycemic during therapy require careful supervision of the dose and frequent feedings for at least 3 to 5 days. Hospitalization and intravenous glucose may be necessary.

Loss of control of blood glucose: When a patient stabilized on any diabetic regimen is exposed to stress such as fever, trauma, infection, or surgery, a loss of control may occur. At such times, it may be necessary to discontinue DIABINESE and administer insulin.

The effectiveness of any oral hypoglycemic drug, including DIABINESE, in lowering blood glucose to a desired level decreases in many patients over a period of time, which may be due to progression of the severity of the diabetes or to diminished responsiveness to the drug. This phenomenon is known as secondary failure, to distinguish it from primary failure in which the drug is ineffective in an individual patient when first given.

ADVERSE REACTIONS

Hypoglycemia: See PRECAUTIONS section.

Gastrointestinal Reactions: Cholestatic jaundice may occur rarely. DIABINESE should be discontinued if this occurs. Gastrointestinal disturbances are the most common reactions; nausea has been reported in less than 5% of patients, and diarrhea, vomiting, anorexia, and hunger in less than 2%. Other gastrointestinal disturbances have occurred in less than 1% of patients including proctocolitis. They tend to be dose related and may disappear when dosage is reduced.

Dermatologic Reactions: Pruritus has been reported in less than 3% of patients. Other allergic skin reactions, e.g., urticaria and maculopapular eruptions have been reported in approximately 1% or less of patients. These may be transient and may disappear despite continued use of DIABINESE; if skin reactions persist the drug should be discontinued.

Porphyria cutanea tarda and photosensitivity reactions have been reported with sulfonylureas. Skin eruptions rarely progressing to erythema multiforme and exfoliative dermatitis have also been reported.

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

Metabolic Reactions: Hepatic porphyria and disulfiram-like reactions have been reported with DIABINESE.

Endocrine Reactions: On rare occasions, chlorpropamide has caused a reaction identical to the syndrome of inappropriate antidiuretic hormone (ADH) secretion. The features of this syndrome result from excessive water retention and include hyponatremia, low serum osmolality, and high urine osmolality.

DOSAGE AND ADMINISTRATION

There is no fixed dosage regimen for the management of diabetes mellitus with DIABINESE or any other hypoglycemic agent. In addition to the usual monitoring of urinary glucose, the patient's blood glucose must also be monitored periodically to determine the minimum effective dose for the patient, to detect primary failure, and to detect secondary failure. Glycosylated hemoglobin levels may also be of value in monitoring the patient's response to therapy.

The total daily dosage is generally taken at a single time each morning with breakfast. Occasionally cases of gastrointestinal intolerance may be relieved by dividing the daily dosage. A LOADING OR PRIMING DOSE IS NOT NECESSARY AND SHOULD NOT BE USED.

Initial Therapy: 1. The mild to moderately severe, middle-aged, stable, non-insulin-dependent diabetic patient should be started on 250 mg daily. Older patients should be started on smaller amounts of DIABINESE, in the range of 100 to 125 mg daily.

2. No transition period is necessary when transferring patients from other oral hypoglycemic agents to DIABINESE. The other agent may be discontinued abruptly and chlorpropamide started at once. In prescribing chlorpropamide, due consideration must be given to its greater potency.

Many mild to moderately severe, middle-aged, stable non-insulin-dependent diabetic patients receiving insulin can be placed directly on the oral drug and their insulin abruptly discontinued. For patients requiring more than 40 units of insulin daily, therapy with DIABINESE may be initiated with a 50 per cent reduction in insulin for the first few days, with subsequent further reductions dependent upon the response.

Five to seven days after the initial therapy, the blood level of chlorpropamide reaches a plateau. Dosage may subsequently be adjusted upward or downward by increments of not more than 50 to 125 mg at intervals of three to five days to obtain optimal control. More frequent adjustments are usually undesirable.

Maintenance Therapy: Most moderately severe, middle-aged, stable non-insulin-dependent diabetic patients are controlled by approximately 250 mg daily. Many investigators have found that some milder diabetics do well on daily doses of 100 mg or less. Many of the more severe diabetics may require 500 mg daily for adequate control. PATIENTS WHO DO NOT RESPOND COMPLETELY TO 500 MG DAILY WILL USUALLY NOT RESPOND TO HIGHER DOSES. MAINTENANCE DOSES ABOVE 750 MG DAILY SHOULD BE AVOIDED.

HOW SUPPLIED: Blue, "D"-shaped, scored tablets in strengths of 100 mg, tablet code 393; 100's, NDC # 0663-3930-66, 500's, NDC # 0663-3930-73, and 100 unit dose of 10 x 10, NDC # 0663-3930-41 and 250 mg, tablet code 394, 100's, NDC # 0663-3940-66, 250's, NDC # 0663-3940-71, 1000's, NDC # 0663-3940-82, 100 unit dose of 10 x 10, NDC # 0663-3940-41, and 30's D-Pak, NDC # 0663-3940-30.

RECOMMENDED STORAGE: Store below 86°F (30°C)

CAUTION: Federal law prohibits dispensing without prescription

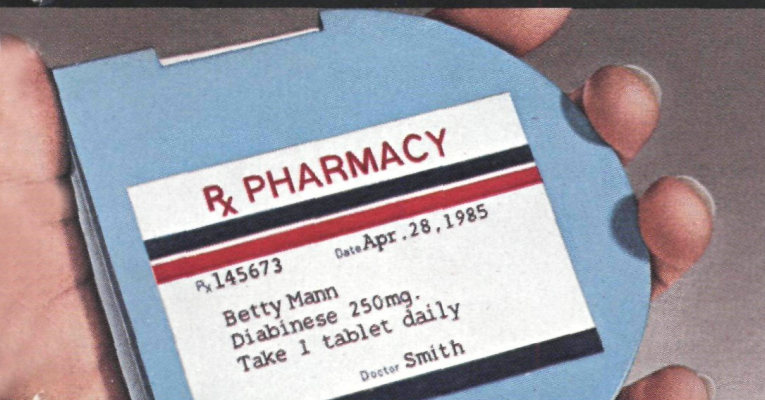


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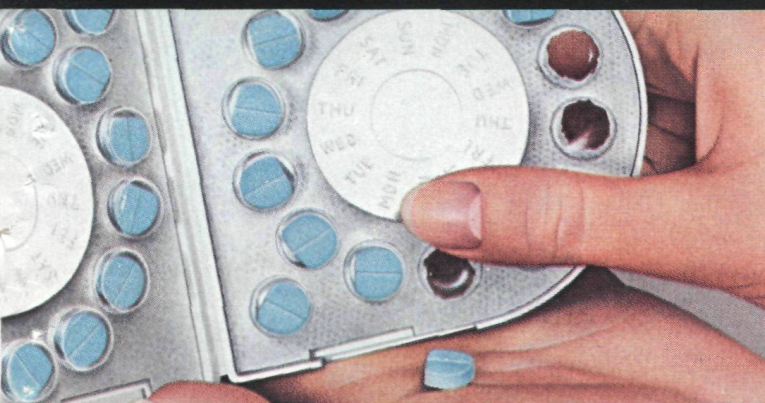
The Diabinese® (chlorpropamide) D-Pak Tablets, USP 250 mg helps your patients remember and keep track of every 250-mg once-a-day dose



The Diabinese D-Pak (dispenser pack), a compliance aid and refill reminder, contains a full 30-tablet supply of Diabinese 250-mg tablets in a lightweight, compact case.



Clearly printed instructions make opening simple...but only for adults. In tests by an independent laboratory, the Diabinese D-Pak exceeded Federal standards for child resistance, and for ease of opening by adults.



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Tablet-for-tablet, the Diabinese D-Pak costs less than Diabinese from pharmacist-stocked bottles of 1,000. This represents two free days of therapy and only a few cents a day more than generic chlorpropamide.

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Diabinese® D-Pak (chlorpropamide) Tablets, USP 250 mg

The case for compliance from

Pfizer LABORATORIES DIVISION
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Please see Diabinese® (chlorpropamide) brief summary on preceding page.

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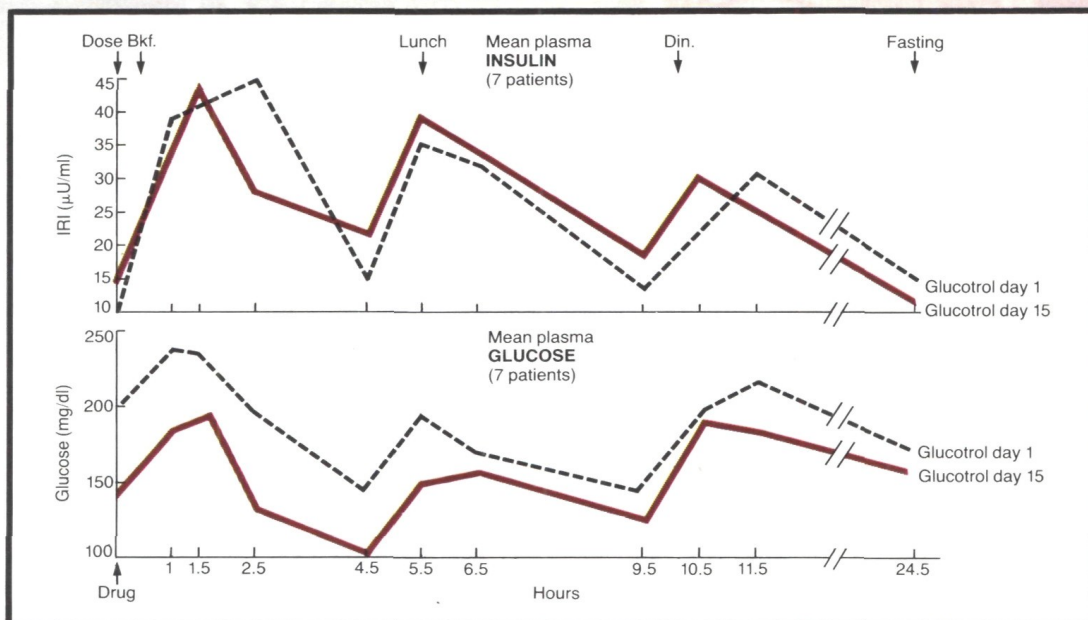
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(glipizide) 5-mg and 10-mg
Scored Tablets

Breaking barriers

more normal insulin release and utilization



(Adapted from Peterson CM, et al¹)

Glucose and insulin response to three standard meals was measured at eleven time points on the first and fifteenth days of administration of Glucotrol (glipizide) to seven patients with NIDDM. The mean dose of Glucotrol was 8.7 mg per day (0.1 mg/kg).

■ Insulin levels rose markedly after the first meal, then dropped, then rose again following subsequent meals.

■ The insulin response pattern with Glucotrol closely simulates the pattern commonly seen in nondiabetics.

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. Melander A, Wåhlin-Boll E: Clinical pharmacology of glipizide, in *Proceedings of a Symposium: New Perspectives in Noninsulin-Dependent Diabetes Mellitus and the Role of Glipizide in Its Treatment*. Am J Med, pp. 41-45, Nov. 30, 1983. 3. Feinglos MN, Lebovitz HE: Long-term safety and efficacy of glipizide, in *Proceedings of a Symposium: New Perspectives in Noninsulin-Dependent Diabetes Mellitus and the Role of Glipizide in Its Treatment*. Am J Med, pp. 60-66, Nov. 30, 1983.

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Long-term metabolic improvement "Long-term therapy with glipizide, in contrast to studies of other sulfonylureas, often results in a sustained increase in glucose-stimulated insulin secretion."³

While controversy remains in the findings of the UGDP, there have been reports of increased cardiovascular risk associated with oral hypoglycemic therapy.

Glucotrol[®]

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

When diet alone fails in non-insulin-dependent diabetes mellitus

Please turn page for Glucotrol[®] (glipizide) prescribing information.

GLUCOTROL® (glipizide) Tablets 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 non-steroidal 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.

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.

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 (glipizide), dialysis is unlikely to be of benefit.

DOSEAGE 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.

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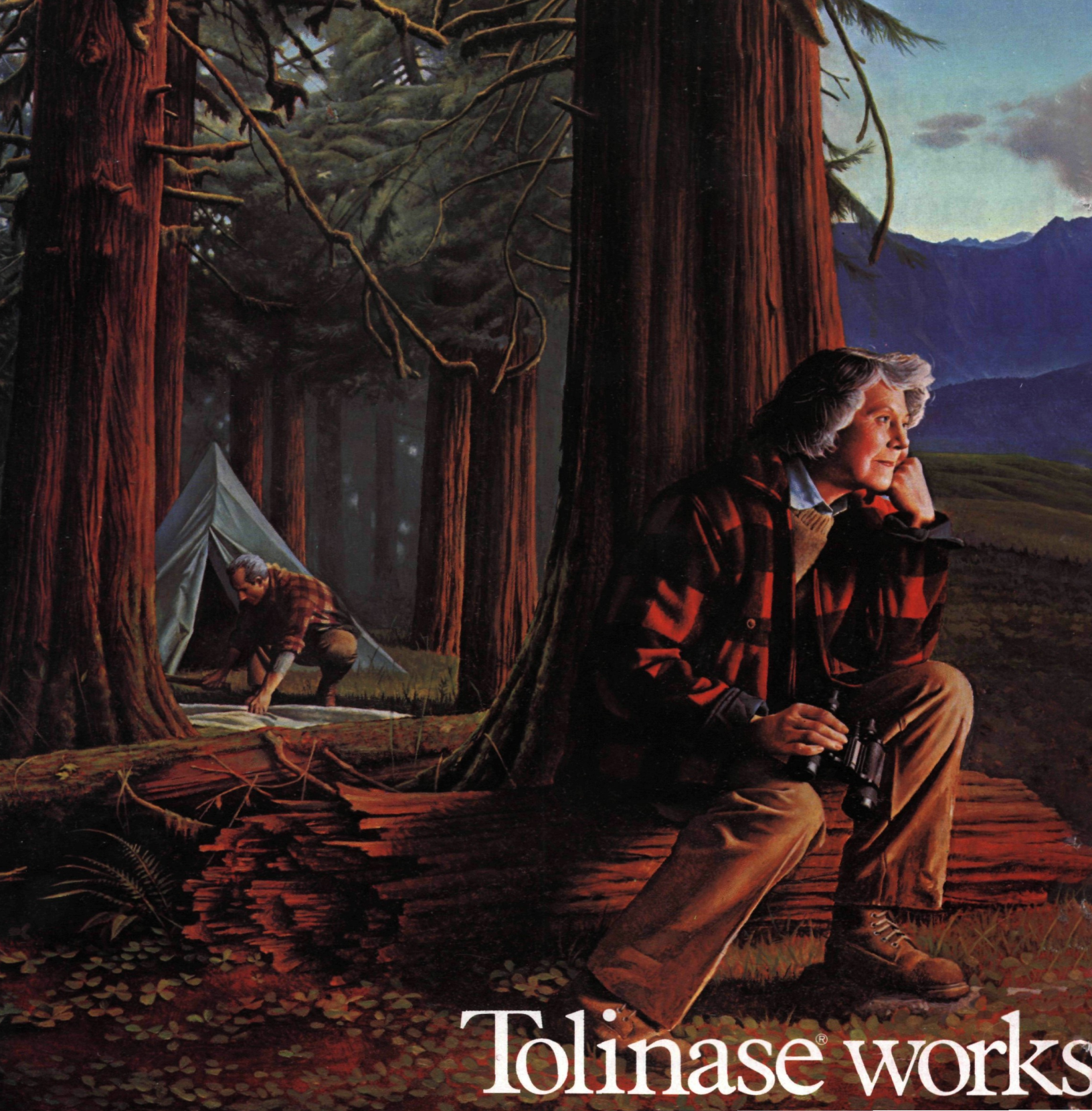
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Tolinase[®] works

Each once-a-day dose of *Tolinase* is effective for about 24 hours once steady state has been achieved—an important consideration in the management of type II diabetic patients. Most of the urinary excretion occurs within the first 24 hours after administration.

When diet and exercise fail to control glucose levels adequately in type II (non-insulin-dependent) diabetes, TOLINASE Tablets (tolazamide) are a sound addition to the regimen—not only because they provide effective, once-a-day therapy, but also because the action of each dose lasts about



one day at a time

24 hours. Proper patient selection, dosage, and instructions are important in order to avoid hypoglycemic episodes.

***Tolinase* causes a mild diuresis—**

an added advantage in patients whose condition may be aggravated by fluid retention (patients with hypertension or congestive heart failure, for example).

Although the interpretations are controversial, the UGDP study reported in 1970 that the use of tolbutamide, an oral hypoglycemic drug, was associated with increased cardiovascular mortality.

In type II diabetes

Tolinase[®] 100, 250, & 500 mg tablets
(tolazamide)

One tablet...one day's therapy

Please turn page for brief summary of prescribing information.

Upjohn The Upjohn Company
Kalamazoo, MI 49001 U.S.A.

In type II diabetes

Tolinase® (tolazamide) 100, 250, & 500 mg tablets

One tablet...one day's therapy

TOLINASE® Tablets (tolazamide) Suggested Initial Dosage

Patient Criteria	TOLINASE Dose
No previous hypoglycemic agent	FBS* level lower than 200 mg% (true) 100 mg/day single dose
	FBS* level greater than 200 mg% (true) 250 mg/day single dose
	Malnourished, underweight, elderly, or poor dietary habits 100 mg/day single dose
Transfer from other hypoglycemic agents	From chlorpropamide 250 mg/day** or tolbutamide more than 1 g/day 250 mg/day single dose
	From tolbutamide 1 g or less/day, or acetohexamide 250 mg/day 100 mg/day single dose
Transfer from insulin	From less than 20 U/day 100 mg/day single dose
	From 20-40 U/day 250 mg/day single dose
	From more than 40 U/day Reduce insulin dosage 50%; begin TOLINASE Tablets 250 mg/day

*See complete prescribing information

**Fasting blood sugar

**See package insert for special precautions when transferring patients from chlorpropamide

CONTRAINDICATIONS

TOLINASE Tablets are contraindicated in patients with:

1. Known hypersensitivity or allergy to the drug.
2. Diabetic ketoacidosis, with or without coma. This condition should be treated with insulin.
3. Type I diabetes mellitus, as sole therapy.

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 [Suppl 2]: 747-830, 1970).

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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 apply to other oral hypoglycemic drugs in this class, in view of their close similarities in mode of action and chemical structure.

PRECAUTIONS - General

Hypoglycemia: All sulfonylureas are capable of producing severe hypoglycemia. Proper patient selection and dosage and instructions are important to avoid hypoglycemic episodes. Patients with renal or hepatic insufficiency, elderly, debilitated or malnourished patients, and those with adrenal or pituitary insufficiency, are particularly susceptible to hypoglycemia. Hypoglycemia may be difficult to recognize in the elderly and in 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: This may occur in diabetic patients exposed to stress such as fever, trauma, infection or surgery. It may then be necessary to discontinue TOLINASE and administer insulin.

Adequate adjustment of dose and adherence to diet should be assessed before classifying a patient as a secondary failure.

Information for Patients: Patients should be informed of the potential risks and advantages of TOLINASE and of alternative modes of therapy. They also should be informed about the importance of adherence 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.

Laboratory Tests: Response to TOLINASE Tablets should be monitored by frequent urine glucose tests and periodic blood glucose tests. Measurement of glycosylated hemoglobin levels may be helpful in some patients.

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.

Certain drugs tend to produce hyperglycemia and may lead to loss of control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid.

Pregnancy: TOLINASE should be used during pregnancy only if clearly needed. Insulin should be used during pregnancy to maintain blood glucose as close to normal as possible. Prolonged severe hypoglycemia (4 to 10 days) has been reported in neonates born to mothers who were receiving a sulfonylurea drug at the time of delivery. TOLINASE should be discontinued at least two weeks before the expected delivery date.

Nursing Mothers: Some sulfonylurea drugs are known to be excreted in human milk. Insulin therapy should be considered.

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

ADVERSE REACTIONS

Hypoglycemia: See Precautions and Overdosage sections. **Gastrointestinal Reactions:** Cholestatic jaundice may occur rarely; TOLINASE Tablets should be discontinued if this occurs. Gastrointestinal disturbances, e.g., nausea, epigastric fullness, and heartburn are the most common reactions (1% of patients). They tend to be dose

related and may disappear when dosage is reduced. **Dermatologic Reactions:** Allergic skin reactions, e.g., pruritus, erythema, urticaria, and morbilliform or maculopapular eruptions occurred in 0.4% of patients. These may be transient and may disappear despite continued use of TOLINASE; if skin reactions persist, the drug should be discontinued. **Porphyrria cutanea tarda** and photosensitivity reactions have been reported with sulfonylureas. **Hematologic Reactions:** Leukopenia, agranulocytosis, thrombocytopenia, hemolytic anemia, aplastic anemia, and pancytopenia have been reported with sulfonylureas. **Metabolic Reactions:** Hepatic porphyria and disulfiram-like reactions have been reported with sulfonylureas; however, disulfiram-like reactions have been reported very rarely. **Miscellaneous:** Weakness, fatigue, dizziness, vertigo, malaise, and headache have infrequently been reported.

OVERDOSAGE

Overdosage of sulfonylureas, including TOLINASE Tablets, 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 which 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.

HOW SUPPLIED

TOLINASE Tablets are available in the following strengths and package sizes:

100 mg (scored, round, white)	Unit-of-Use bottles of 100	NDC 0009-0070-02
250 mg (scored, round, white)	Bottles of 200	NDC 0009-0114-04
	Bottles of 1000	NDC 0009-0114-02
	Unit-of-Use bottles of 100	NDC 0009-0114-05
	Unit-Dose package of 100	NDC 0009-0114-06
500 mg (scored, round, white)	Unit-of-Use bottles of 100	NDC 0009-0477-06

Caution: Federal law prohibits dispensing without prescription. Store at controlled room temperature 15°-30°C (59°-86°F). Dispensed in well closed containers with safety closures. Keep container tightly closed. B-11-S

For additional product information see your Upjohn representative.

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July, 1985



Position in Diabetes Research

The Julia McFarlane Diabetes Research Unit at The University of Calgary seeks a new Faculty Member with expertise in Immunology in the area of diabetes mellitus research, with special emphasis on cell-mediated immunity. Candidates must be qualified to compete for funds from the Alberta Heritage Foundation for Medical Research or the Medical Research Council of Canada. Remuneration will be based on faculty rank salary scales at The University of Calgary. Rank will be based on qualifications and research experience. All qualified individuals are encouraged to apply but preference will be given to Canadian citizens and permanent residents. Deadline for receipt of applications is November 30, 1985.

Please send curriculum vitae and names of three referees to:

Dr. D.A.K. Roncari, Director
Julia McFarlane Diabetes Research Unit
Faculty of Medicine
Health Sciences Centre
Room 2559
3330 Hospital Drive N.W.
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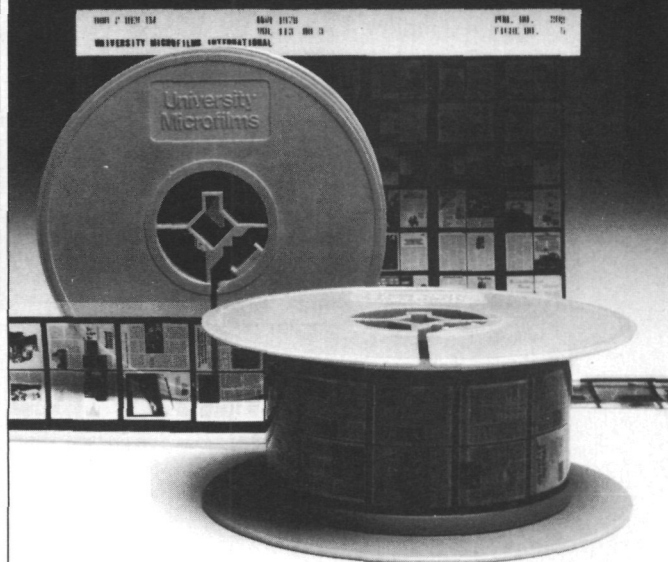
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ANNOUNCES

25 ADDITIONAL GRANTS TOWARD A BETTER UNDERSTANDING OF DIABETES

The Trustees of the Foundation are pleased to announce the funding of 25 more special projects. Nine grants have been awarded in basic research, eight in clinical research, and eight in education.

Basic Research Grants:

George Liang King, M.D.
Joslin Diabetes Center,
Boston, MA.

"Comparative Analysis of Vascular Cells from Capillaries and Large Arteries from Diabetic and Non-Diabetic Humans and BB/W Rats."

Roger H. Unger, M.D.
University of Texas Southwestern Medical School, Dallas, TX.
"The Role of Hyperglycemia in Beta Cell Damage."

Joseph R. Williamson, M.D.
Washington University School of Medicine, St. Louis, MO.
"Diabetes-Induced Leukocyte Dysfunction: Is It Also an Aldose Reductase-Linked Phenomenon?"

Douglas L. Coleman, Ph.D.
The Jackson Laboratory,
Bar Harbor, ME.
"Etiocolanones: New Oral Anti-Diabetes and Anti-Obesity Agents."

Gegham Barseghian, M.D.
City of Hope National Medical Center, Duarte, CA.
"Potentiation of Insulin Activity by Ethanolamine."

Stephen Brendan Richardson, M.D.
Department of Medicine, New York University School of Medicine,
New York, NY.
"Insulin Secretion from RINm Cells: A Possible Model for Non-Insulin-Dependent Diabetes Mellitus (NIDDM)."

Robert C. McEvoy, M.D.
Mount Sinai School of Medicine,
New York, NY.
"Development of Cell Lines of Mouse and Human Pancreatic Beta Cells."

Madhur K. Sinha, Ph.D.
East Carolina University School of Medicine, Greenville, NC.
"Demonstration of Insulin Mediator in Serum and Urine: Its Significance in NIDDM."

Carl Grunfeld, M.D., Ph.D.
Department of Medicine, University of California, San Francisco, CA.
"Structure and Function Analysis of the Insulin Receptor Using Antibodies Against Sequence Specific Peptides."

Clinical Research Grants:

Neil B. Ruderman, M.D.
Boston University School of Medicine, Boston, MA.
"Exercise, Thermogenesis and Control of Body Weight."

Donald C. Simonson, M.D.
Yale University School of Medicine,
New Haven, CT.
"Glucose Resistance in Diabetes."

Lalith K. Misra, Ph.D.
Baylor College of Medicine,
Houston, TX.
"Diabetic Neuropathy: A Nuclear Magnetic Resonance Study."

Elliot J. Rayfield, M.D.
Mount Sinai School of Medicine,
New York, NY.
"The Effect of Serum Glucose on Neutrophil Function in Diabetic Patients."

Harvey Jon Kliman, M.D., Ph.D.
Hospital of the University of Pennsylvania, Philadelphia, PA.
"Differentiation and Growth of the Human Trophoblast: The Effects of Insulin and Insulin-like Growth Factors."

Ronald B. Goldberg, M.D.
University of Miami School of Medicine, Miami, FL.
"Remnant Lipoproteins in Type I and II Diabetes Mellitus: Influence of Good Glycemic Control."

Alain D. Baron, M.D.
University of California,
San Diego, CA.
"In Vivo Regulation of Non-insulin Mediated Glucose Uptake in Man."

Richard C. Spielman, Ph.D.
University of Pennsylvania School of Medicine, Philadelphia, PA.
"Family Studies of the Insulin Gene Polymorphism in Type I and II Diabetes."

Education Grants:

Adrienne B. Butler, M.D.
Southeast Health Unit, Waycross, GA.
"Project Retreat: Recreation, Training and Eating Outdoors for Youth With Diabetes."

O. Charles Olson, M.D.
Deaconess Medical Center,
Spokane, WA.
"Is Diabetes Education Effective in Improving the Prognosis for Diabetic Patients?"

Ellie Strock, R.N.
International Diabetes Center,
Minneapolis, MN.
"Diabetes Home Care Program."

Richard R. Rubin, Ph.D.
Johns Hopkins Diabetes Center,
Baltimore, MD.
"Evaluation of an Intensive Diabetes Education Program Incorporating Coping Skills Training."

Marla Bernbaum, M.D.
St. Louis University School of Medicine, St. Louis, MO.
"A Clinical Program for the Visually Impaired Diabetic Patient."

Maria Luisa Urdaneta, R.N., Ph.D.
Social Science Research Administration, San Antonio, TX.
"The Impact of Sociocultural Factors on Compliance to Treatment Regimens Among Mexican American Diabetics."

Jeanne B. Groner, M.S.W.
New York College of Podiatric Medicine, New York, NY.
"Comprehensive Diabetic Information Program."

Linda F. Samson, M.N., R.N.C.
University of Pennsylvania, Philadelphia, PA.
"Survey of Major Perceived Problems of Diabetics During Pregnancy."

Continuation of the Foundation's work is insured by an annual donation derived from a percentage of sales of diabetes products marketed by Hoechst-Roussel Pharmaceuticals Inc.

For further information on the Foundation, write to Herbert Rosenkilde, M.D., Executive Director, Diabetes Research and Education Foundation, Inc., P.O. Box 6168, Bridgewater, NJ 08807-9998.

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