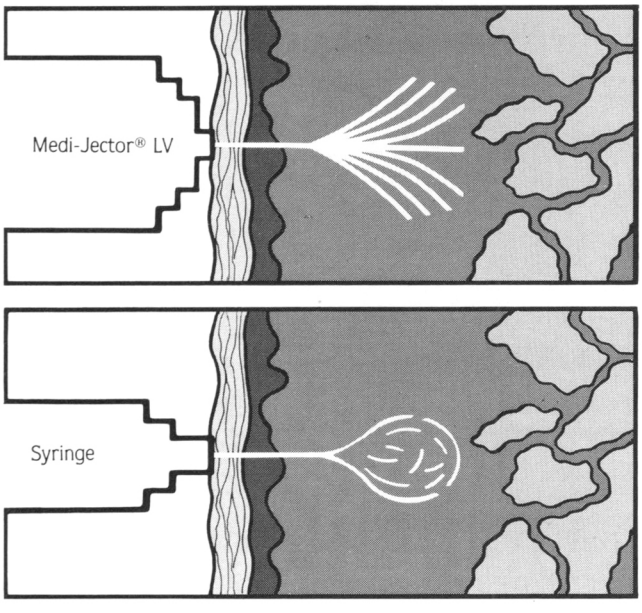
Your patients may not have a choice about taking insulin.

They should have a choice about how they take it.

"It's not so bad; you'll get used to the needle."

What else could you tell the diabetic who must take insulin? After all, taking insulin is life-sustaining to many, while for others it is the best way to control blood sugar and retard or prevent life-threatening complications. Your challenge is to obtain maximum compliance, for effective control.

The reality, however, is that puncturing the skin with a needle is neither normal nor something to look forward to with anything but resignation, and for various psychosocial or physical reasons something that can be painful.



Even patients must tell themselves, "It's not so bad."

How else could they cope with up to 1,000 punctures a year? How many of your patients would rather live without needle injections and still have the maximum benefit of insulin therapy?

Medi-Jector® Needleless Injection: a better choice for compliance, control and comfort.

The development of Medi-Jector's needleless injection technology has paralleled the evolution of modern diabetes management, with its goal of improved control facilitated by self blood glucose monitoring and multiple daily doses of insulin.

The prospect of multiple daily injections cannot be pleasant for patients who have found one shot a day to be painful, or for patients who have never taken insulin before. Such fear of needle punctures can result in a detrimental compliance problem.

Medi-Jector is a precision, mechanically-powered injection device, proven in over seven years of patient use by thousands of diabetics.

Medi-Jector forces insulin, under pressure, through a tiny orifice which produces a liquid column that is **one-third** the size of the smallest needle. After penetration, the insulin is rapidly dispersed through the planes of least resistance as a fine spray. Penetration depth is adjustable to accommodate individual and site-to-site variation in skin resistance. Nothing touches the patient but the tiny column of insulin. Compared to needle injections, there is less tissue trauma, greater insulin dispersion and improved absorption. Most important, the injection sensation is virtually undetectable.

Medi-Jector users tell us they could no longer conceive of taking multiple injections with a needle, and most say they never want to "see" an insulin syringe again.

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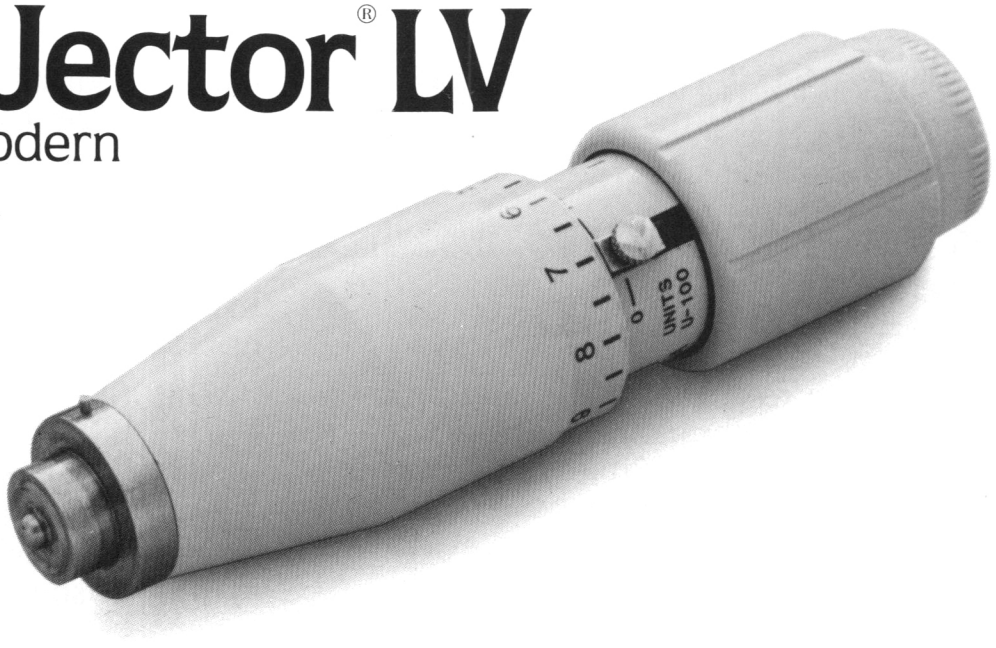
designed for modern insulin therapy



Derata Corporation, a pioneer in the research and development of insulin jet injector systems, designed its third generation system to meet the needs of modern multiple insulin injection therapy.

Medi-Jector LV delivers up to 50 units of U-100 (single or mixed doses) with unequaled comfort. Confirmed accuracy (tenths of a unit) delivers precise doses, time after time.

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Simple operation and available training materials makes patient instruction easy and effective. Continuing customer support services ensure patient confidence and maximum utilization.

Medi-Jector LV is classified as durable medical equipment and is 80% to 100% covered by many insurance plans. Additionally, the Derata Corporation is so confident of the quality and comfort of the Medi-Jector LV that it is sold with a prorated money-back guarantee and warranteed for five years. Medi-Jector LV will provide your patients years of economical, effective insulin delivery with a comfort unequaled by insulin syringes.

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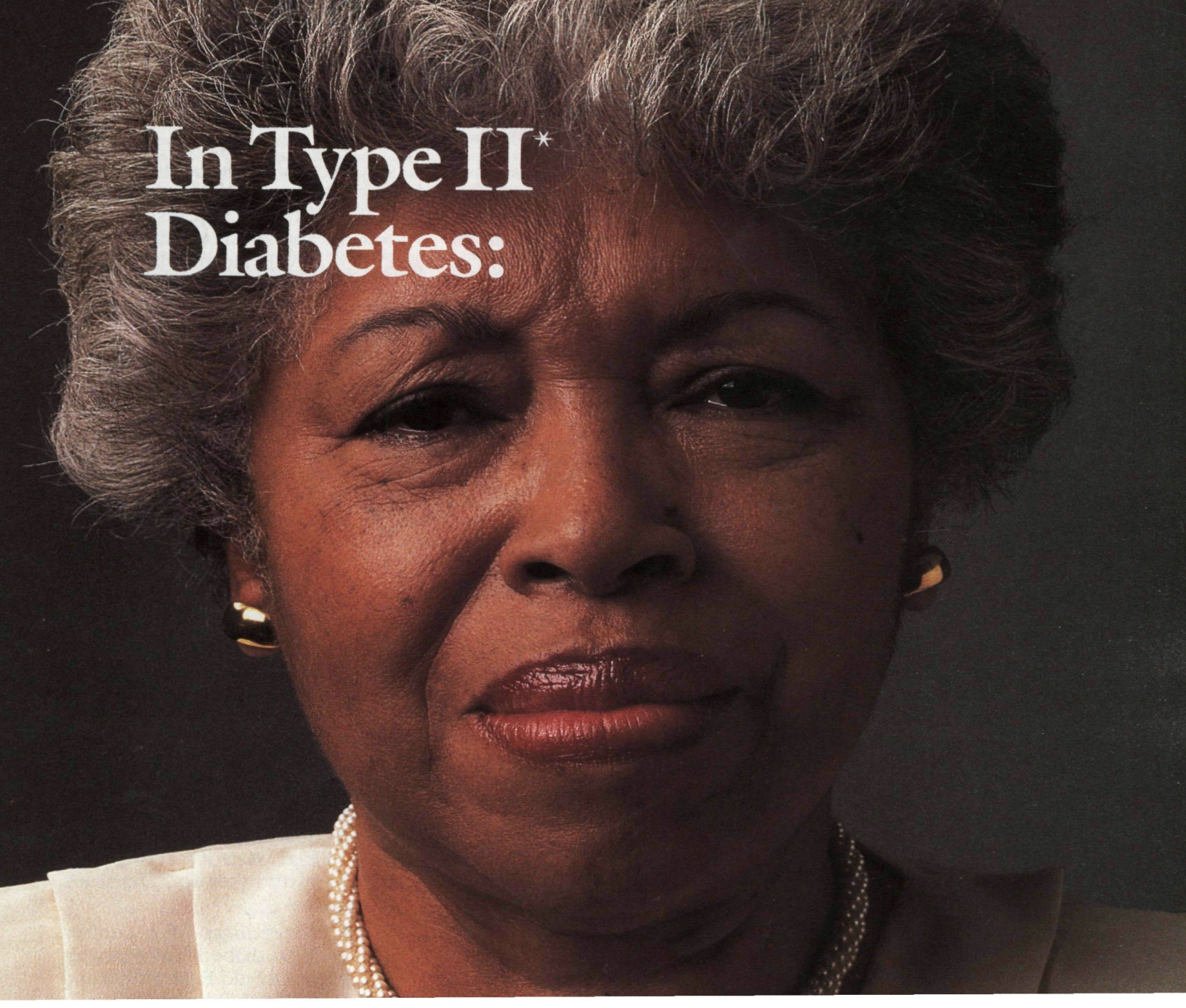
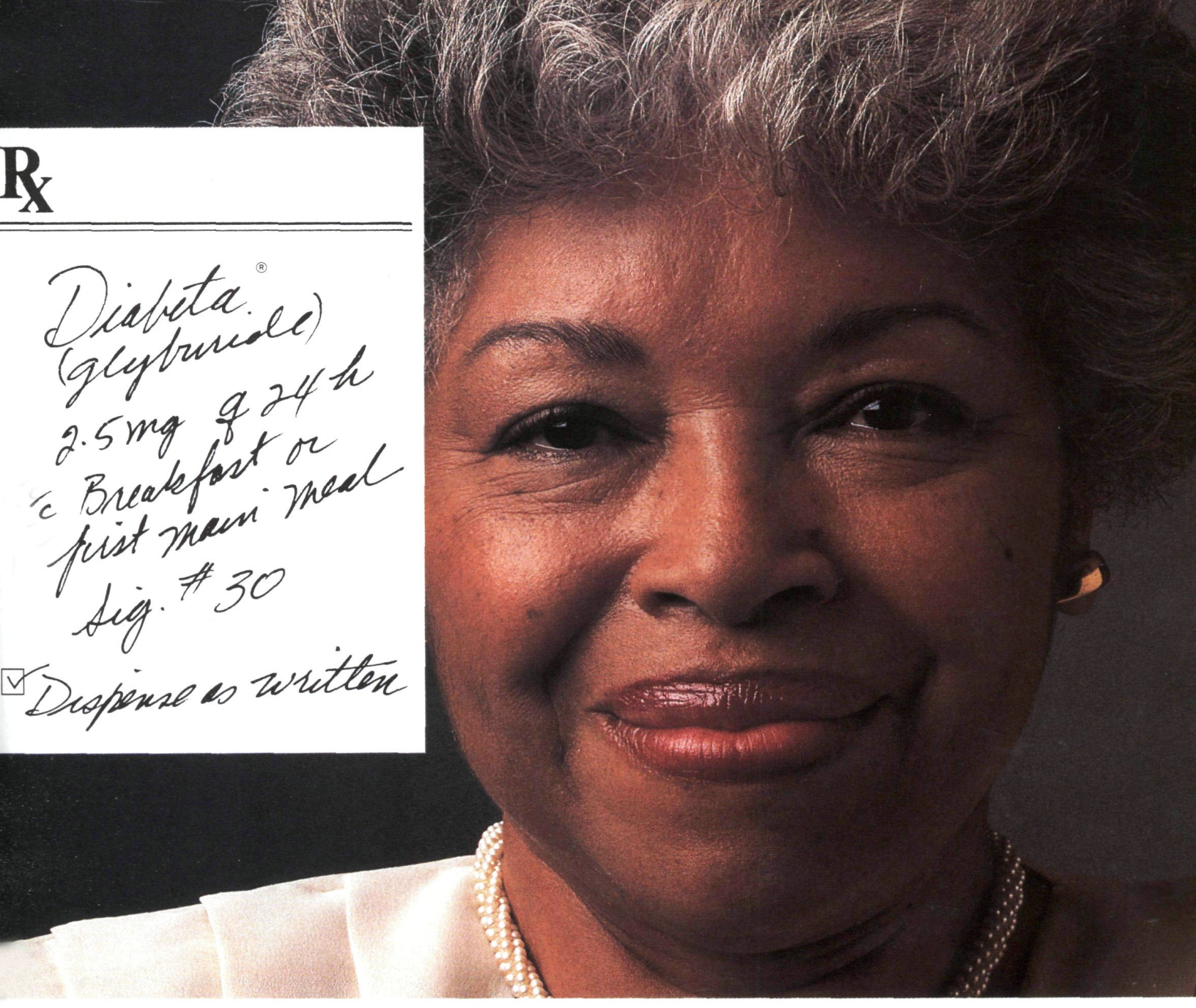


When persistent hyperglycemia or adverse effects signal the need for a change—

*Non-insulin-Dependent Diabetes Mellitus (NIDDM)

Although the findings are controversial, the UGDP study reported in 1970 that the use of tolbutamide, an oral sulfonylurea, was associated with increased cardiovascular risk.



Consider the world's most prescribed oral hypoglycemic agent:

Control: High success rate** (77%-100%) reported in Type II diabetics who fail on diet alone.

Effective in some patients who fail on other oral agents.

Compliance: Simple one-a-day dosage regimen for most patients.

Low incidence of side effects.

Confidence: Safety proven in over 15 years of clinical use.

DIET &

Diaβeta® TABLETS 1.25, 2.5 and 5mg

(GLYBURIDE)

**Data on file, Hoechst-Roussel Pharmaceuticals Inc.

See following page for brief summary of prescribing information.

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THE WORLD'S MOST PRESCRIBED ORAL HYPOGLYCEMIC AGENT

DiaBeta® (glyburide) Tablets 1.25, 2.5 and 5 mg

BRIEF SUMMARY

INDICATIONS AND USAGE

DiaBeta® (glyburide) is indicated as an adjunct to diet to lower the blood glucose in patients with non-insulin-dependent diabetes mellitus (Type II) whose hyperglycemia cannot be controlled by diet alone.

In initiating treatment for non-insulin-dependent diabetes, diet should be emphasized as the primary form of treatment. Caloric restriction and weight loss are essential in the obese diabetic patient. Proper dietary management alone may be effective in controlling the blood glucose and symptoms of hyperglycemia. The importance of regular physical activity should also be stressed, and cardiovascular risk factors should be identified and corrective measures taken where possible.

If this treatment program fails to reduce symptoms and/or blood glucose, the use of an oral sulfonylurea or insulin should be considered. Use of DiaBeta® (glyburide) must be viewed by both the physician and patient as a treatment in addition to diet, and not as a substitute for diet or as a convenient mechanism for avoiding dietary restraint. Furthermore, loss of blood glucose control on diet alone may be transient, thus requiring only short-term administration of DiaBeta® (glyburide).

During maintenance programs, DiaBeta® (glyburide) should be discontinued if satisfactory lowering of blood glucose is no longer achieved. Judgments should be based on regular clinical and laboratory evaluations.

In considering the use of DiaBeta® (glyburide) in asymptomatic patients, it should be recognized that controlling the blood glucose in non-insulin-dependent diabetes has not been definitely established to be effective in preventing the long-term cardiovascular or neural complications of diabetes.

CONTRAINDICATIONS

DiaBeta® (glyburide) 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 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 DiaBeta® (glyburide) 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 DiaBeta® (glyburide) 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.

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 DiaBeta® (glyburide) and administer insulin.

The effectiveness of any oral hypoglycemic drug, including DiaBeta® (glyburide), 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.

Information for patients

Patients should be informed of the potential risks, advantages, alternative modes of therapy, importance of adherence to dietary instructions, to a regular exercise program, and regular testing of urine and/or blood glucose. Also explain to the patient and responsible family members, the risks of hypoglycemia, its symptoms, treatment, conditions that predispose to its development, and primary and secondary failure.

Laboratory Tests

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

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. When such drugs are administered to a patient receiving DiaBeta® (glyburide), the patient should be observed closely for hypoglycemia. When such drugs are withdrawn from a patient receiving DiaBeta® (glyburide), the patient should be observed closely for loss of control.

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. When such drugs are administered to a patient receiving DiaBeta® (glyburide), the patient should be closely observed for loss of control. When such drugs are withdrawn from a patient receiving DiaBeta® (glyburide), the patient should be observed closely for hypoglycemia.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

DiaBeta® (glyburide) is non-mutagenic when studied in the Salmonella microsome test (Ames test) and in the DNA damage/alkaline elution assay. Studies in rats at doses up to 300 mg/kg/day for 18 months showed no carcinogenic effects.

Pregnancy

Teratogenic Effects: Pregnancy Category B

Reproduction studies have been performed in rats and rabbits at doses up to 500 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to DiaBeta® (glyburide). There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. 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 (4 to 10 days) 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. If DiaBeta® (glyburide) is used during pregnancy, it should be discontinued at least two weeks before the expected delivery date.

Nursing Mothers

Although it is not known whether DiaBeta® (glyburide) is excreted in human milk, some sulfonylureas are known to be excreted in human milk. Because the potential for hypoglycemia in nursing infants may exist, a decision should be made whether to discontinue nursing or to discontinue administering the drug, taking into account the importance of the drug to the mother. If DiaBeta® (glyburide) is discontinued and if diet alone is inadequate for controlling blood glucose, 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; DiaBeta® (glyburide) should be discontinued if this occurs. Gastrointestinal disturbances, e.g., nausea, epigastric fullness, and heartburn, are the most common reactions and occur in 1.8% of treated 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, occur in 1.5% of treated patients. These may be transient and may disappear despite continued use of DiaBeta® (glyburide); if skin reactions persist, the drug should be discontinued.

Porphyria 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 reactions have been reported with sulfonylureas; however, these have not been reported with DiaBeta® (glyburide). Disulfiram-like reactions have been reported very rarely with DiaBeta® (glyburide).

OVERDOSAGE: Overdosage can produce hypoglycemia. Aggressively treat the mild symptoms (without loss of consciousness or neurologic findings) with oral glucose and adjustments in drug dosage and/or meal patterns. Continue close monitoring until patient is out of danger. Severe hypoglycemic reactions with coma, seizure, or other neurological impairment, are medical emergencies requiring immediate hospitalization. With hypoglycemic coma (diagnosed or suspected), administer rapid intravenous injection of concentrated (50%) glucose solution, followed by continuous infusion of a more dilute (10%) glucose solution at a rate to maintain a blood glucose level above 100 mg/dL. Monitor closely for a minimum of 24-48 hours; hypoglycemia may recur after apparent clinical recovery.

YOUR PRESCRIPTIONS FOR DIABETA® (GLYBURIDE) SUPPORT

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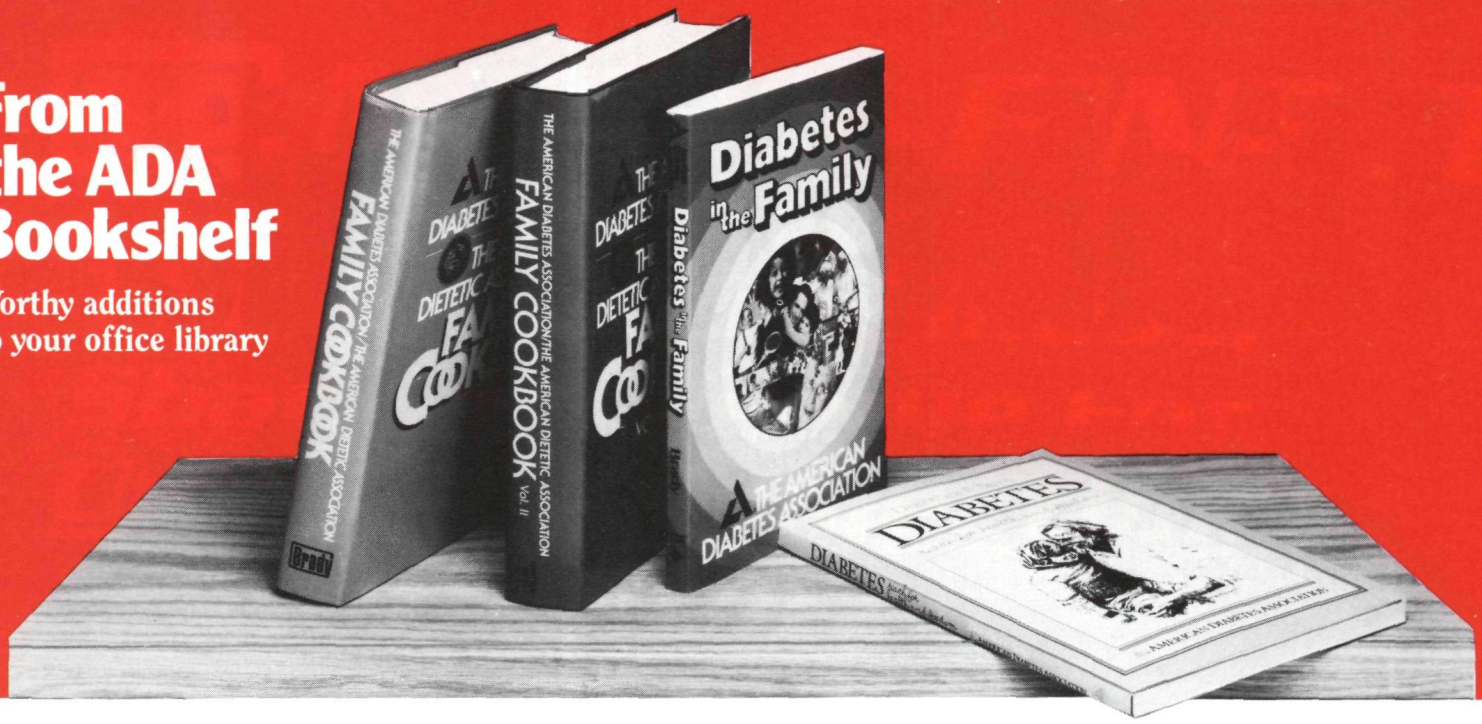

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Here is all the information you and your family need. This comprehensive reference book on diabetes addresses your questions, concerns, and hopes for the future with accurate and up-to-date information. Chapters on the nature of diabetes and adjusting to it . . . information on daily care, diet, testing, exercise, stress . . . lifetime considerations such as careers, marriage, travel, pregnancy . . . how to be prepared for emergencies . . . diabetes and the family and much more. Over 200 pages of valuable diabetes data.

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The American Diabetes Association/ The American Dietetic Association

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Diabetologia

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Organ of the European Association for the Study of Diabetes (EASD)

Volume 29 Number 3 March 1986

Originals

A. M. Umpleby, M. A. Boroujerdi, P. M. Brown, E. R. Carson, P. H. Sönksen
The effect of metabolic control on leucine metabolism in Type 1 (insulin-dependent) diabetic patients **131**

O. Gedik, S. Akalin
Effects of vitamin D deficiency and repletion on insulin and glucagon secretion in man **142**

A. Hørlyck, H. J. G. Gundersen, R. Østerby
The cortical distribution pattern of diabetic glomerulopathy **146**

J. L. Wautier, H. LeBlanc, M. P. Wautier, E. Abadie, P. Passa, J. P. Caen
Erythrocyte adhesion to cultured endothelium and glycaemic control in Type 1 (insulin-dependent) diabetic patients **151**

R. J. Young, C. C. A. Macintyre, C. N. Martyn, R. J. Prescott, D. J. Ewing, A. F. Smith, G. Viberti, B. F. Clarke
Progression of subclinical polyneuropathy in young patients with Type 1 (insulin-dependent) diabetes: associations with glycaemic control and microangiopathy (microvascular complications) **156**

T. Baba, S. Murabayashi, T. Ishizaki, Y. Ido, K. Aoyagi, K. Takebe
Renal kallikrein in diabetic patients with hypertension accompanied by nephropathy **162**

N. E. Cameron, M. B. Leonard, I. S. Ross, P. H. Whiting
The effects of Sorbinil on peripheral nerve conduction velocity, polyol concentrations and morphology in the streptozotocin-diabetic rat **168**

F. Kaufmann, C. Lacoste
Vitreous fluorescein accumulation determined by in vivo fluorophotometry and by vitreous extraction in normal and diabetic rats **175**

L. B. Dahlin, K. F. Meiri, W. G. McLean, B. Rydevik, J. Sjöstrand
Effects of nerve compression on fast axonal transport in streptozotocin-induced diabetes mellitus. An experimental study in the sciatic nerve of rats **181**

B. T. Mossman, C. M. Ireland, M. Filipak, S. LeDoux, G. L. Wilson
Comparative interactions of streptozotocin and chlorozotocin with DNA of an insulin-secreting cell line (RINr) **186**

E. W. Kraegen, D. E. James, L. H. Storlien, K. M. Burleigh, D. J. Chisholm
In vivo insulin resistance in individual peripheral tissues of the high fat fed rat: assessment by euglycaemic clamp plus deoxyglucose administration **192**

S. Sandler, A. Andersson
Long-term effects of exposure of pancreatic islets to nicotinamide in vitro on DNA synthesis, metabolism and B-cell function **199**

Letters to the Editor

F. J. Grundbacher
Genetics of Type 1 (insulin-dependent) diabetes **203**

G. A. A. Ferns, R. C. Trembath, G. A. Hitman, D. J. Galton
Reply from the authors **204**

G. Williams, J. Pickup
Aprotinin on insulin absorption and subcutaneous blood flow **204**

J. Reckless
Diet and Type 1 (insulin-dependent) diabetes **205**

Erratum **205**

Organisation section/Announcements **206**

Indexed in Current Contents

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125 Diabetologia - ISSN 0012-186X DBTGAJ 29 (3) 131-206 (1986)

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1. Shapiro, B., et al.: *Diabetes Care* 4:396-403, 1981.

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Reference
1. Gadia M, Salzman R, Lauritano AA, et al: summary data available on request.

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