VOLUME 13 NUMBER 8 AUGUST 1990

DIABETES CARE®

THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

American Diabetes Association®

ISSN 0149-5992

A JOURNAL OF THE AMERICAN DIABETES ASSOCIATION

In non-insulin-dependent diabetes...

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When diet and exercise aren't enough, once-a-day MICRONASE provides 24-hour control of both postprandial and fasting blood glucose levels. The usual starting dosage, 2.5 mg to 5 mg once a day, should be taken with breakfast or the first main meal of the day. Some patients, particularly those receiving more than 10 mg daily, may have a more satisfactory response with twice-a-day dosage.

All sulfonylureas, including MICRONASE, can cause severe hypoglycemia. Proper patient selection, dosage, and instructions are important.

Micronase®

Tablets (glyburide) **Usual starting dosage 2.5 mg-5 mg once a day**

Please see adjacent page for brief summary of prescribing information.

AUGUST AUTHOR INDEX
(Volume 13, Number 8)

VOLUME 13 NUMBER 8
AUGUST 1990

DIABETES CARE®

THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

Mission Statements for *Diabetes Care* and *Diabetes*

***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.**

***Diabetes* publishes original research about the physiology and pathophysiology of diabetes mellitus. Submitted manuscripts can report any aspect of laboratory, animal, or human research. Emphasis is on investigative reports focusing on areas such as the pathogenesis of diabetes and its complications, normal and pathologic pancreatic islet function and intermediary metabolism, pharmacological mechanisms of drug and hormone action, and biochemical and molecular aspects of normal and abnormal biological processes. Studies in the areas of diabetes education or the application of accepted therapeutic and diagnostic approaches to patients with diabetes mellitus are not published.**

All manuscripts and other editorial correspondence should be sent by first class mail to David C. Robbins, MD, Editor, *Diabetes Care*, Medical Research Foundation, George Hyman Memorial Research Building, 108 Irving Street, NW, Washington, DC 20010. 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.

Diabetes Care publishes only original material. When submitting a manuscript, authors must state in their transmittal letter that the material has not been previously published or is not currently being submitted to another journal.

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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Diabetes Care is listed in *Science Citation Index, Current Contents/Life Sciences, Current Contents/Clinical Medicine, SCISEARCH, ISI/BIOMED* databases, and *Automatic Subject Citation Alert. Diabetes Care* is available online on *BRS Colleague*. For more information call 800-468-0908. It is also available in machine-readable format from University Microfilms International. *Diabetes Care* is printed on acid-free paper starting with Vol. 11(1), 1988.

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PRT-085

IN THIS ISSUE

By the Skin of Our Teeth

Periodontal disease is one of the major causes of tooth loss in adults. It is considered more common in diabetic than in nondiabetic subjects and can make glycemic control more difficult to achieve. There are few longitudinal studies of periodontal disease in people with diabetes and most studies have included only insulin-dependent diabetes mellitus subjects. In this issue, Nelson et al. (p. 836) evaluated the development of advanced periodontal disease in 2273 Pima Indians followed between 1983 and 1989. When first evaluated, ~66% of the subjects with non-insulin-dependent diabetes mellitus had periodontal disease compared with ~33% of those without diabetes. As expected, incidence increased with age, but the rate of progression or development of new disease was 2.6 times greater in diabetic Pima Indians than in those without diabetes. Although gingival disease is extremely common in older people, with or without diabetes, this study shows that the risk is significantly higher in diabetic subjects. They advocate routine dental examinations and good oral hygiene as part of the standard care for diabetic subjects.

Wellness or Illness: The Dietary Dynamics

Anyone who has struggled with weight control knows the difficulty of changing old eating habits. For people with non-insulin-dependent diabetes mellitus (NIDDM), dietary change can mark the difference between good health and illness. Although diet is a cornerstone in the management of NIDDM, current educational approaches are often ineffective and achieve only temporary change. Campbell et al. (p. 841) designed an intensive educational program to improve dietary patterns and achieve optimal glycemic control. The 11-wk program provided simplified information, repetition, and a cognitive motivational approach to dietary change. They then compared it with a conventional educational program. They found that the intensive program met with greater success than the conventional program in improving dietary compliance, dietary intake, and total cholesterol level in NIDDM patients but it did not necessarily improve glycemic control. Further study of this important area is indicated for the future.

Keeping Score Does Not Add Up

For several decades, the effect of the number of pregnancies on subsequent development of non-insulin-dependent diabetes mellitus (NIDDM) has been a matter of research. A correlation between the number of pregnancies and incidence of NIDDM has been widely accepted. This association is challenged by Boyko et al. (p. 848). They used an extensive survey to examine the effects of childbearing on glucose intolerance and NIDDM prevalence. They found no evidence to suggest that childbearing independently causes an increase in NIDDM prevalence. Instead, they used statistical analysis to conclude that age and body weight are more important determinants of NIDDM than childbearing.

Albumin Excretion Rate: A Matter of Time

What is the best way to measure microalbuminuria? Various studies have used different methods of specimen collection to measure albumin excretion rate (AER). This study, by Wiegmann et al. (p. 864), was undertaken to assess the usefulness of different techniques for determination of AER. They studied 90 patients with type I (insulin-dependent) diabetes and 45 with type II (non-insulin-dependent) diabetes at an outpatient clinic. All were free of overt kidney disease. They compared timed day, night, and 24-h specimens and timed spot specimens during water-induced diuresis. Significant differences in AER were observed depending on the collection technique. They conclude that day or 24-h specimen collection is most useful in determining the presence of abnormal AER, and recommend that it should be used for long-term follow-up of the diabetic patient.

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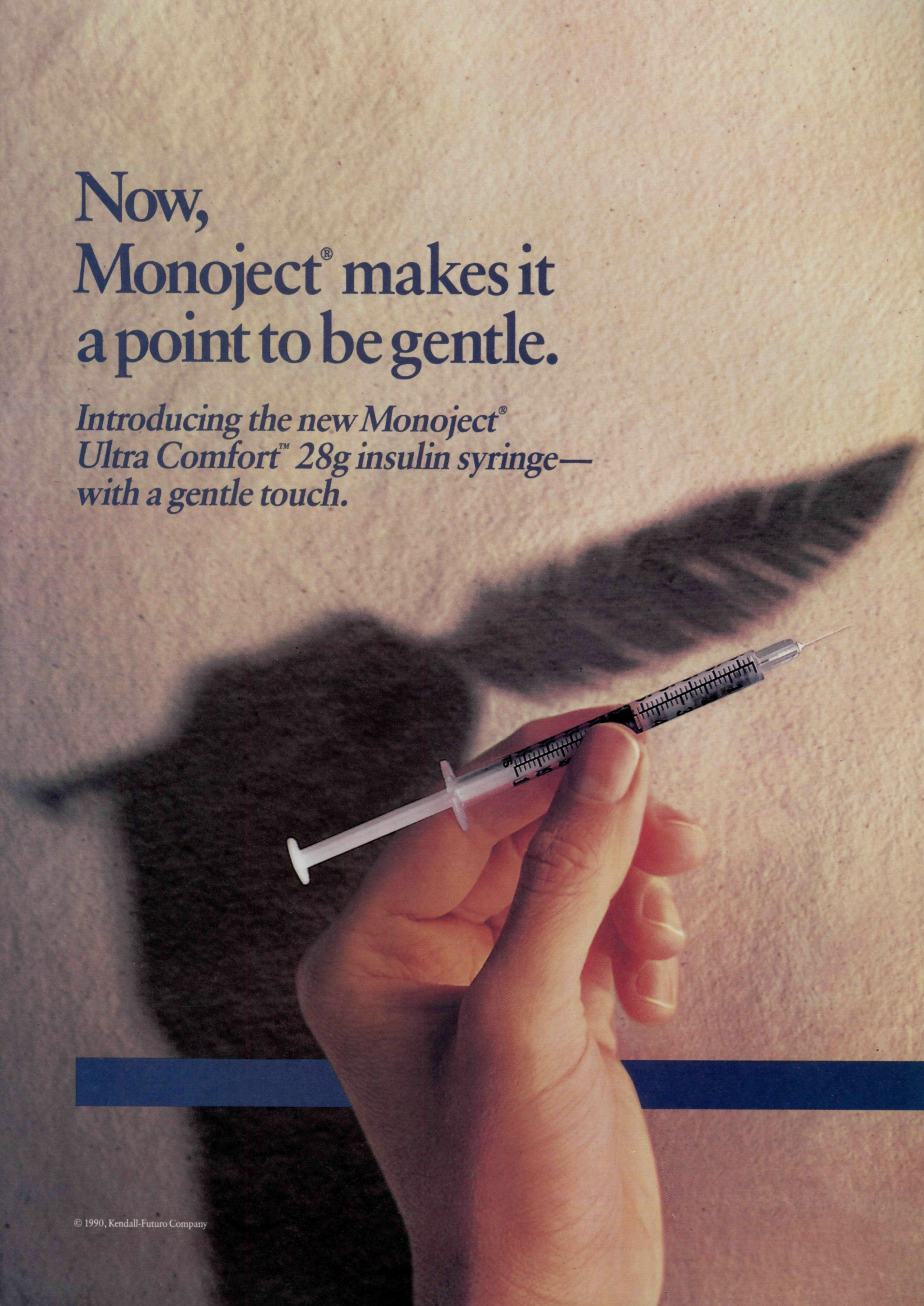
Introducing the new Monoject® Ultra Comfort™ 28g insulin syringe— with a gentle touch.



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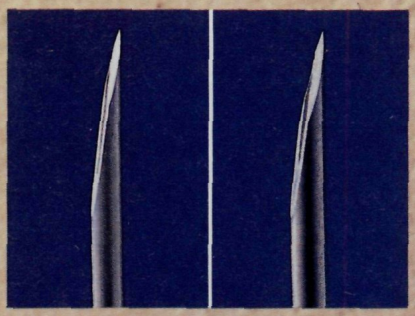

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In comparative studies, patients rated injections with the new Monoject® Ultra Comfort™ 28g insulin syringe *more comfortable* than injections with their current brand of syringe.[1]

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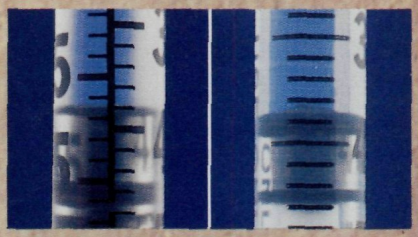

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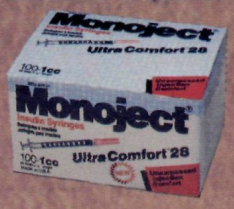


ames

The facts behind the Glucometer® 3

Diabetes Care System with Glucofilm® Test Strips

To make the right recommendation about a blood glucose monitoring system demands all the facts on reliability and ease of use. All the facts about the GLUCOMETER® 3 Diabetes Care System and GLUCOFILM® Test Strips clearly make it the right system for more patients.

Fact: Provides accuracy for professionals, adds simplicity for patients.

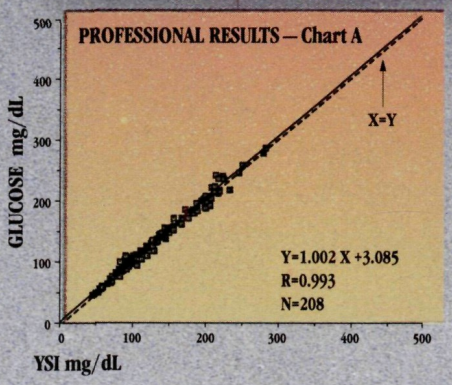
A measuring range of 20-500 mg/dL assures you of clinically useful blood glucose results for good diabetes management. One-button operation, easy-to-see display and film-strip accuracy assure patients of simple, yet confident testing. In charts A and B, our data from experienced evaluators and patients with diabetes who tested themselves support high-level accuracy for both groups. The close correlation of GLUCOMETER 3 System values with the Yellow Springs Instrument (YSI) reference method shows this system is right for all.

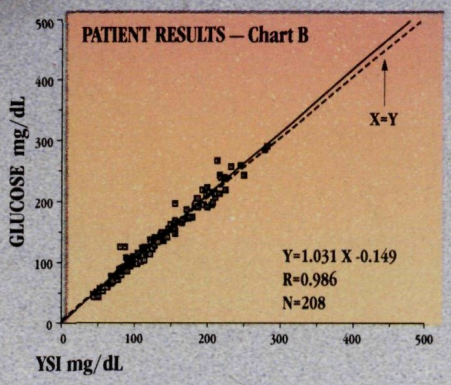
Fact: GLUCOFILM Test Strips provide the widest hematocrit range available for blood glucose levels from 20-500 mg/dL.

Hematocrit levels from 20% to 60% have shown no significant effect on blood glucose results.

Fact: GLUCOMETER 3 Diabetes Care System is affordable.

Be your own judge of the facts behind this reliable, easy-to-use and affordable blood glucose monitoring system. Contact your Miles Inc., Diagnostics Division representative or write us.





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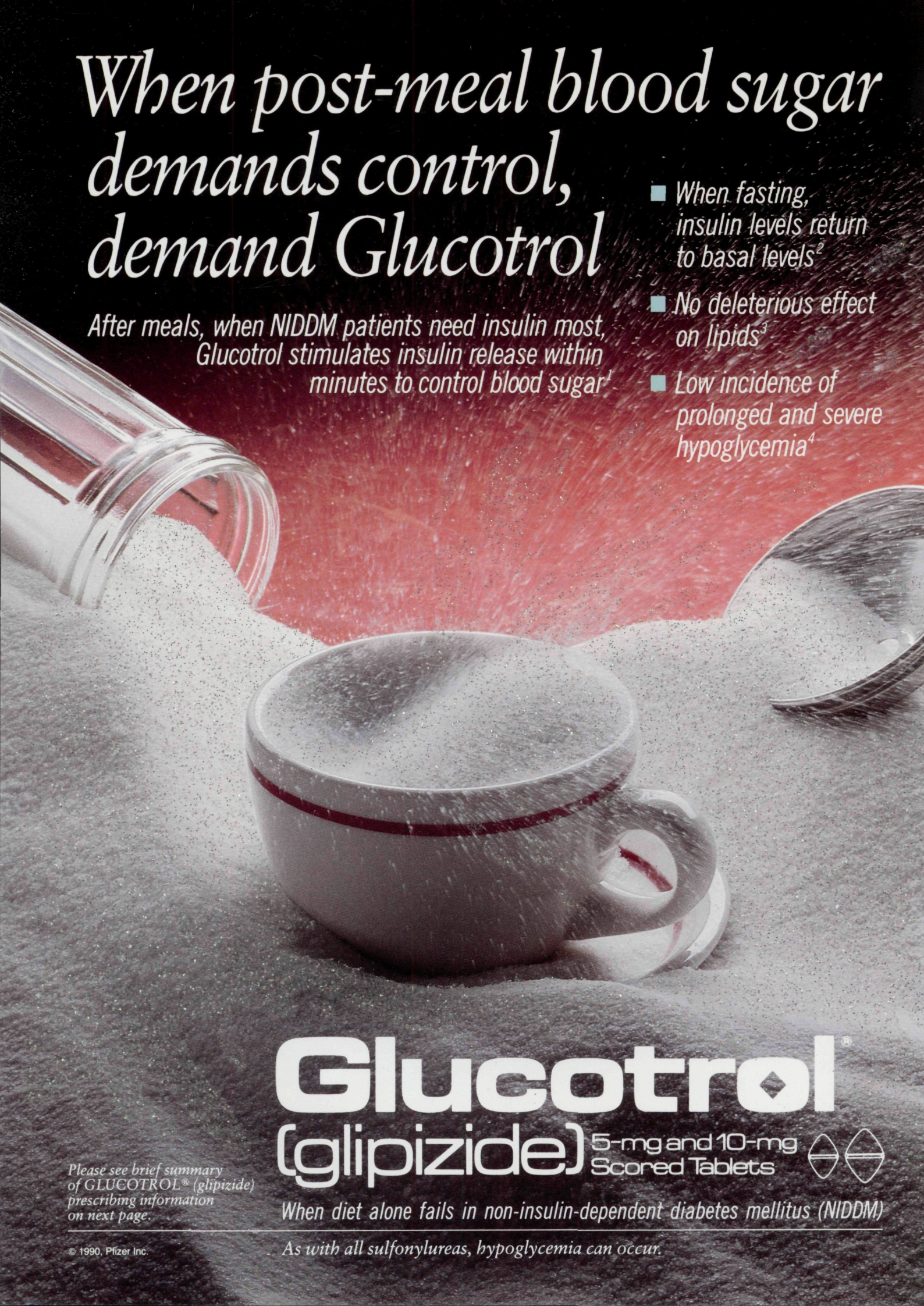
When post-meal blood sugar demands control, demand Glucotrol

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.

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diabetes

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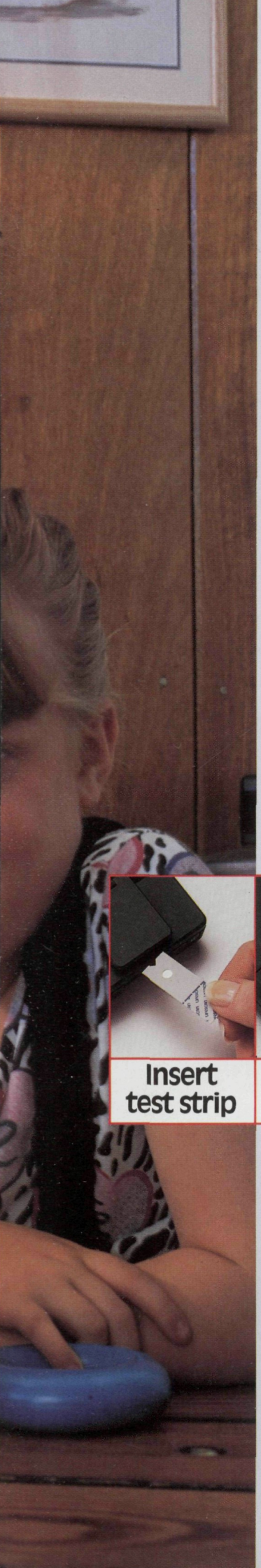

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1. Jovanovic-Peterson L., Peterson C., Dudley J., Kilo C., Ellis B.: Identifying sources of error in self-monitoring of blood glucose. Diabetes Care 1988; 11 (10) 791-794.

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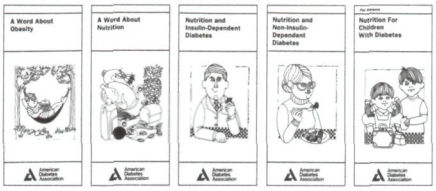
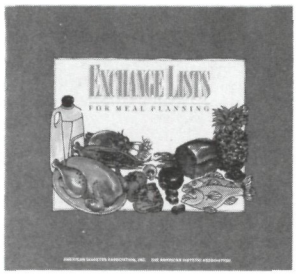


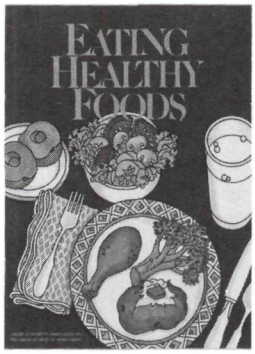
Exchange Lists For Meal Planning

Here's the preferred system for diabetes meal planning. Colorful charts, helpful tips on good nutrition, and the six easy-to-use food exchange lists show your patients how to balance their diets to help control their diabetes. *Regular or Large-Print Versions.*



Eating Healthy Foods

Developed for people with limited reading skills, this colorfully illustrated booklet provides daily meal choices using the Exchange Lists. It's also perfect for patients needing a simplified guide to meal planning.



Nutrition Pamphlets

This series of pamphlets for your patients answers the most commonly asked questions about healthy eating. Each pamphlet contains dietary goals and tips.

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- A Word About Nutrition #228B
- Nutrition and Insulin-Dependent Diabetes #229B
- Nutrition and Non-Insulin-Dependent Diabetes #230B
- Nutrition For Children With Diabetes #231B

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Healthy Food Choices

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Regular	$31.10	$ 62.15	$119.00	$269.00	$547.00
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Spanish	$ 7.55	$ 14.40	$ 25.70	$ 58.70	$106.75
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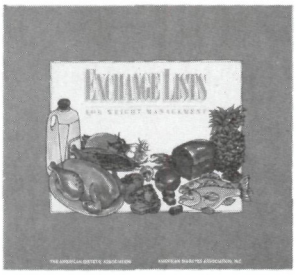

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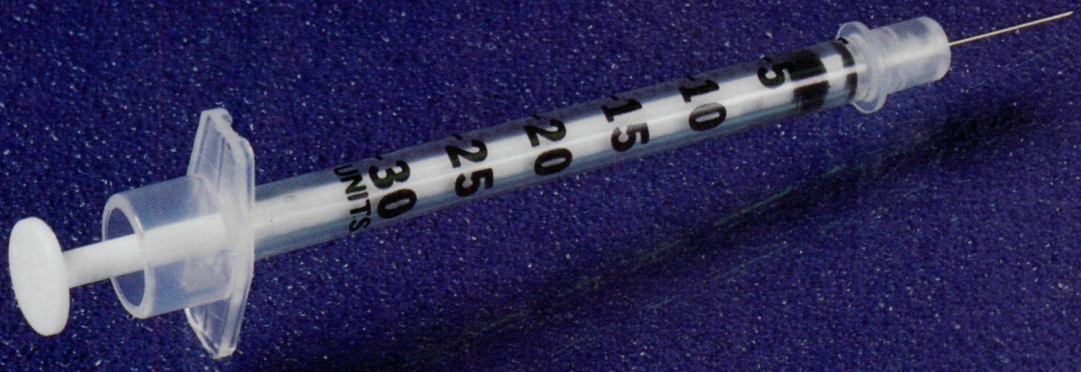

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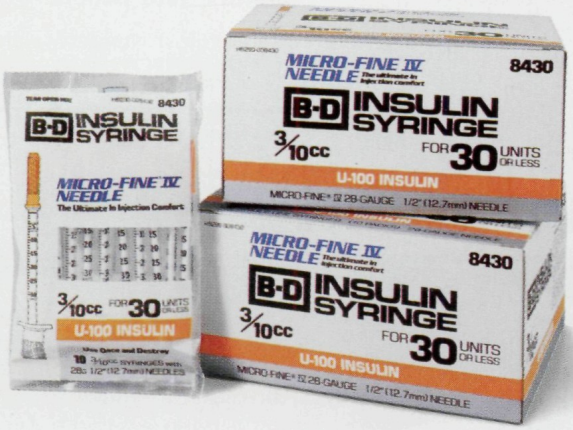

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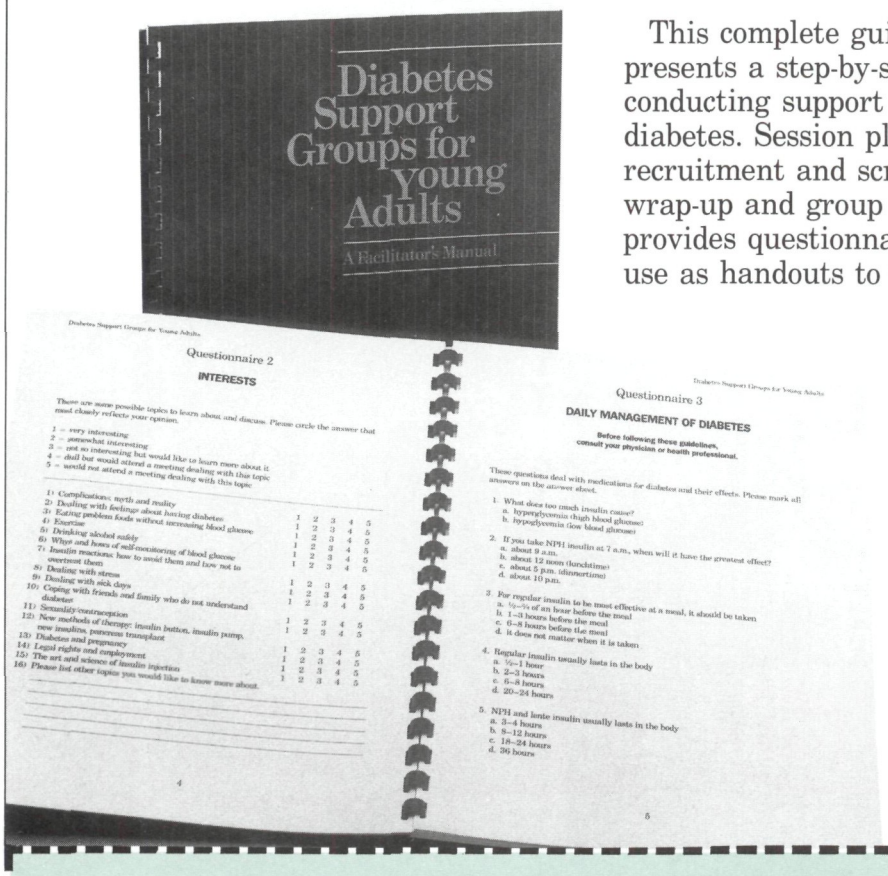

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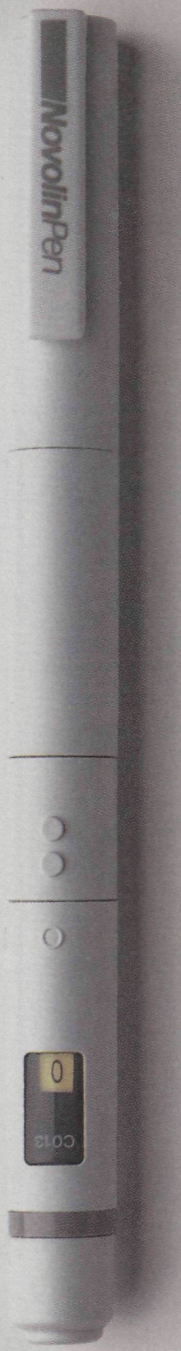

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