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VOLUME 18 NUMBER 6

Diabetes Care

JUNE 1995

Original Articles

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Review Article

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American Diabetes Association.

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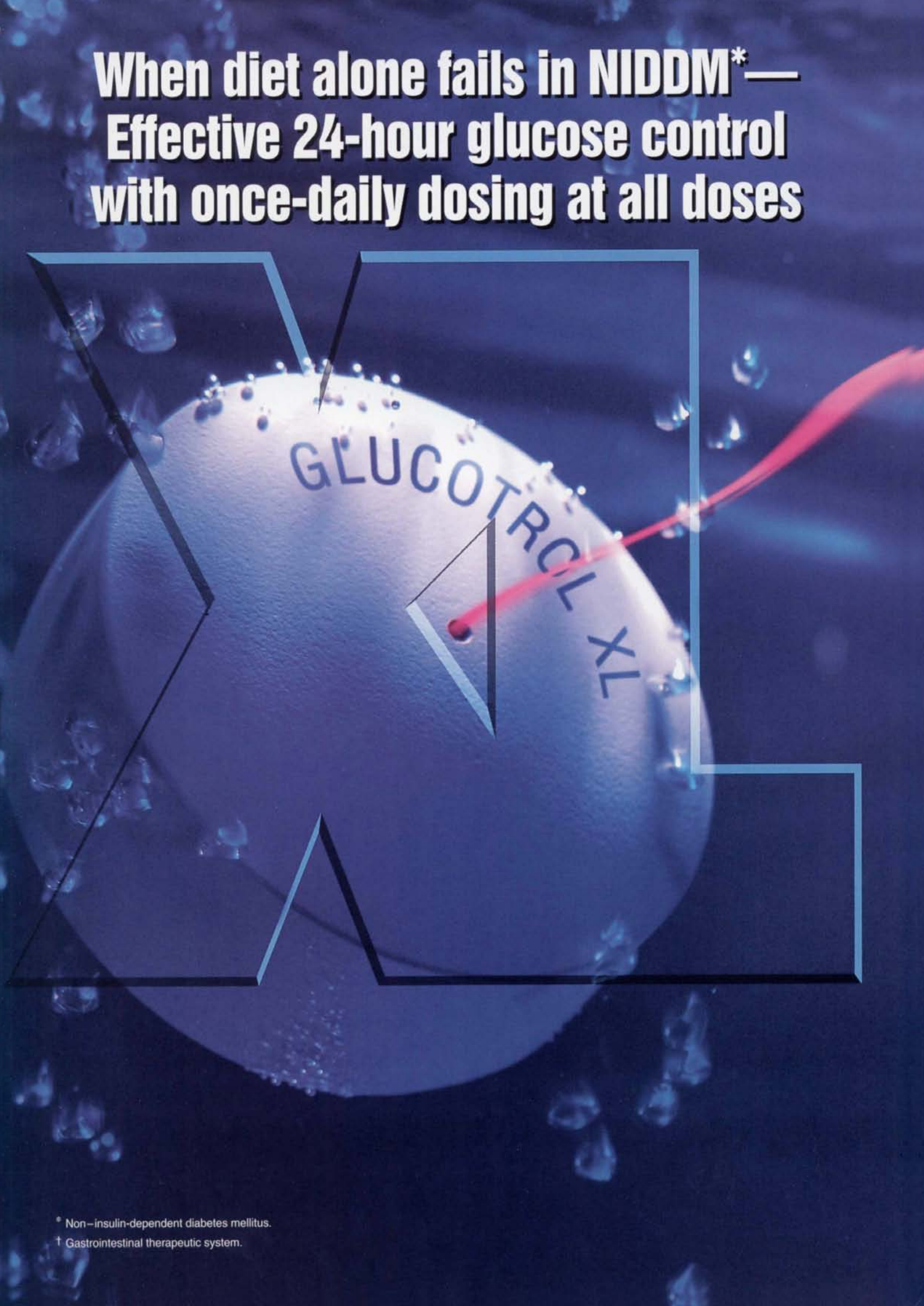
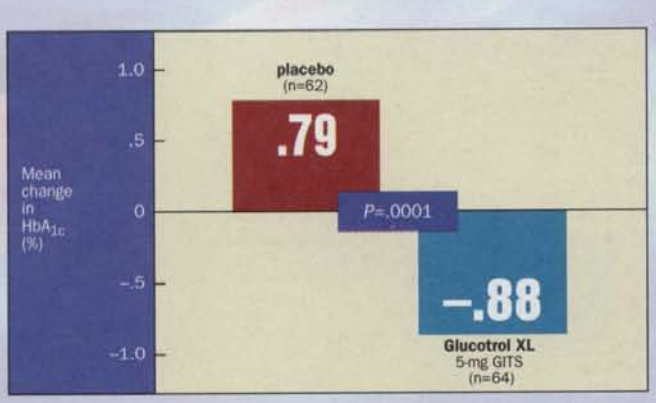
When diet alone fails in NIDDM*— Effective 24-hour glucose control with once-daily dosing at all doses



* Non–insulin-dependent diabetes mellitus.

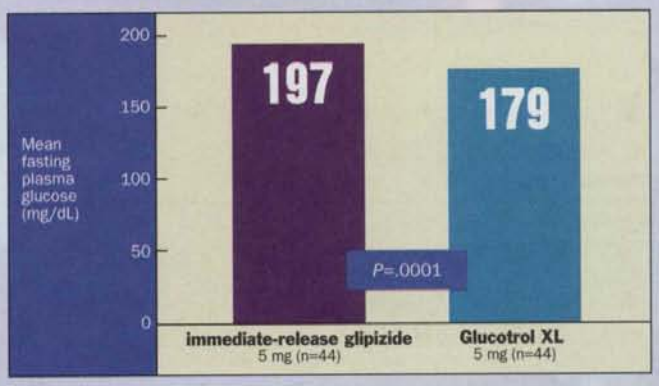
† Gastrointestinal therapeutic system.

Significant decrease in glycosylated hemoglobin (HbA_{1c}) vs placebo[1]



A pooled analysis of two16-week, multicenter, randomized, double-blind, placebo-controlled, fixed-dose studies. After a 1-week washout from current sulfonylurea therapy, or diet failures, patients received 3 weeks of placebo. Following a 4-week titration period in a fixed, double-blind regimen, patients were treated with the assigned dose for 8 weeks.[1]

Significantly lower fasting plasma glucose (FPG) levels and equivalent HbA_{1c} concentrations compared with immediate-release glipizide[1]



Glucotrol XL™ (glipizide) extended release tablets and immediate-release glipizide were compared in a 16-week, multicenter, open-label, crossover study. The data represent the final FPG levels after 8 weeks of each treatment.[1]

Glucotrol XL is well tolerated[1]

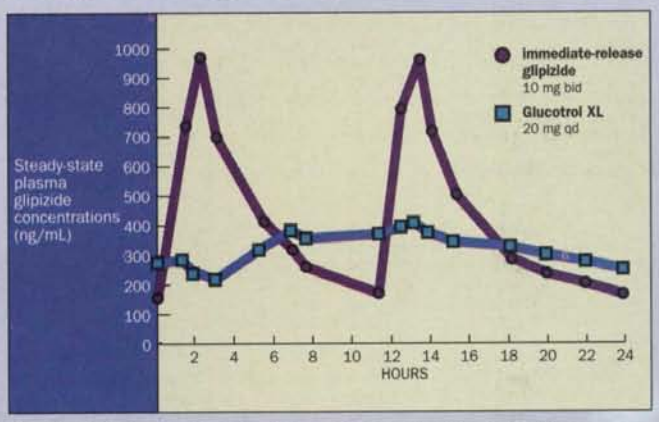
Adverse experiences reported with an incidence of 3% or more[1]

	placebo (%) (n=69)	Glucotrol XL (%) (n=278)
Asthenia	13.0	10.1
Headache	8.7	8.6
Dizziness	5.8	6.8
Diarrhea	0.0	5.4†
Nervousness	2.9	3.6
Tremor	0.0	3.6
Flatulence	1.4	3.2

†Only diarrhea was statistically significant vs placebo.

Incidence of hypoglycemia in 580 patients, who received Glucotrol XL in doses ranging from 5 mg to 60 mg, was 3.4%; only 2.6% of patients discontinued due to hypoglycemia. None of the patients required hospitalization. In the controversial UGDP study, there have been reports of increased cardiovascular risk associated with hypoglycemic therapy.[1]

Glucotrol XL maintains consistent drug levels throughout the day and night[1]



Glucotrol XL 20 mg qd or immediate-release glipizide 10 mg bid were studied in a 5-day, open, randomized, multiple-dose, two-way, crossover study of 20 male patients with NIDDM. Mean glipizide concentration-time profiles on day 5 are shown.[1]

When diet alone fails in NIDDM...

ONCE DAILY **Glucotrol XL**™

(glipizide) extended release

Tablets 5 mg and 10 mg GITS†

As with all sulfonylureas, hypoglycemia may occur.

Please see brief summary of prescribing information on last page.

When diet alone fails in NIDDM...

ONCE DAILY Glucotrol XL™

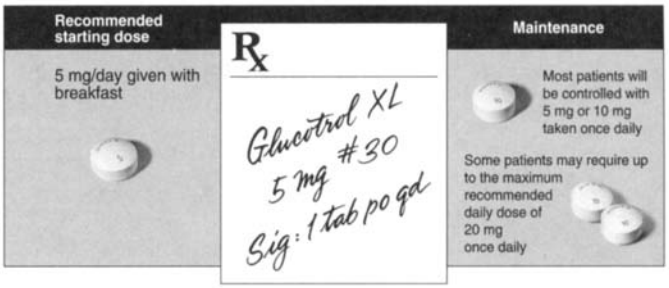
(glipizide) extended release

Tablets 5 mg and 10 mg GITS

- No need to dose 30 minutes before a meal
- Optimal patient care requires careful titration to the lowest effective dose when using all oral sulfonylureas
- Continued monitoring of HbA_{1c} or FPG levels is recommended throughout therapy

Reference: 1. Data on file.

Flexible dosing schedule



Brief Summary of Prescribing Information

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

CONTRAINDICATIONS: Glipizide is contraindicated in patients with: 1. Known hypersensitivity to the drug and 2. Diabetic ketoacidosis, with or without coma. This condition 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.

As with any other non-deformable material, caution should be used when administering GLUCOTROL XL Extended Release Tablets in patients with preexisting severe gastrointestinal narrowing (pathologic or iatrogenic). There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of another drug in this non-deformable sustained release formulation.

PRECAUTIONS: Renal and Hepatic Disease: The pharmacokinetics and/or pharmacodynamics of glipizide may be affected in patients with impaired renal or hepatic function. If hypoglycemia should occur in such patients, it may be prolonged and appropriate management should be instituted.

GI Disease: Markedly reduced GI retention times of the GLUCOTROL XL Extended Release Tablets may influence the pharmacokinetic profile and hence the clinical efficacy of the drug.

Hypoglycemia: All sulfonylurea drugs are capable of producing severe hypoglycemia. Renal or hepatic insufficiency may affect the disposition of glipizide 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 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 glipizide and administer insulin. Adequate adjustment of dose and adherence to diet should be assessed before classifying a patient as a secondary failure.

Laboratory Tests: Blood and urine glucose should be monitored periodically. Measurement of hemoglobin A_{1c} may be useful.

Information for Patients: Patients should be informed that GLUCOTROL XL Extended Release Tablets should be swallowed whole. Patients should not chew, divide or crush tablets. Patients should not be concerned if they occasionally notice in their stool something that looks like a tablet. In the GLUCOTROL XL Extended Release Tablet, the medication is contained within a nonabsorbable shell that has been specially designed to slowly release the drug so the body can absorb it. When this process is completed, the empty tablet is eliminated from the body.

Patients should be informed of the potential risks and advantages of GLUCOTROL XL and of alternative modes of therapy. They should also be informed about 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 also should 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 binding studies with human serum proteins indicate that glipizide binds differently than tolbutamide and does not interact with salicylate or dicumarol. However, caution must be exercised in extrapolating these findings to the clinical situation and in the use of glipizide with these drugs.

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.

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. The effect of concomitant administration of Diflucan© (fluconazole) and Glucotrol® has been demonstrated in a placebo-controlled crossover study in normal volunteers. All subjects received Glucotrol alone and following treatment with 100 mg of Diflucan© as a single daily oral dose for 7 days. The mean percentage increase in the Glucotrol AUC after fluconazole administration was 56.9% (range: 35 to 81%).

Carcinogenesis, Mutagenesis, Impairment of Fertility: A twenty month study in rats and an eighteen 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: 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 glipizide. In studies in rats and rabbits no teratogenic effects were found. There are no adequate and well controlled studies in pregnant women. Glipizide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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 glipizide is used during pregnancy, it should be discontinued at least one month before the expected delivery date.

Nursing Mothers: Although it is not known whether glipizide is excreted in human milk, some sulfonylurea drugs are known to be excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug. If the drug 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.

Geriatric Use: Of the total number of patients in clinical studies of GLUCOTROL XL, 33 percent were 65 and over. No overall differences in effectiveness or safety were observed between these patients and younger patients, but greater sensitivity of some individuals cannot be ruled out. Approximately 1-2 days longer were required to reach steady state in the elderly. (See CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS: In U.S. controlled studies the frequency of serious adverse experiences reported was very low and causal relationship has not been established. The 580 patients from 31 to 87 years of age who received GLUCOTROL XL Extended Release Tablets in doses from 5 mg to 60 mg in both controlled and open trials were included in the evaluation of adverse experiences. All adverse experiences reported were tabulated independently of their possible causal relation to medication.

Hypoglycemia: See PRECAUTIONS and OVERDOSAGE sections.

In double-blind, placebo-controlled studies the adverse experiences reported with an incidence of 3% or more in GLUCOTROL XL-treated patients (N=278) and placebo-treated patients (N=69), respectively, include: Asthenia - 10.1% and 13.0%; Headache - 8.6% and 8.7%; Dizziness - 6.8% and 5.8%; Nervousness - 3.6% and 2.9%; Tremor - 3.6% and 0.0%; Diarrhea - 5.4% and 0.0%; Flatulence - 3.2% and 1.4%.

The following adverse experiences occurred with an incidence of less than 3% in GLUCOTROL XL-treated patients: Body as a whole - pain; Nervous system - insomnia, paresthesia, anxiety, depression and hypesthesia; Gastrointestinal - nausea, dyspepsia, constipation and vomiting; Metabolic - hypoglycemia; Musculoskeletal - arthalgia, leg cramps and myalgia; Cardiovascular - syncope; Skin - sweating and pruritus; Respiratory - rhinitis; Special senses - blurred vision; Urogenital - polyuria.

Other adverse experiences occurred with an incidence of less than 1% in GLUCOTROL XL-treated patients: Body as a whole - chills; Nervous system - hypertonia, confusion, vertigo, somnolence, gait abnormality and decreased libido; Gastrointestinal - anorexia and trace blood in stool; Metabolic - thirst and edema; Cardiovascular - arrhythmia, migraine, flushing and hypertension; Skin - rash and urticaria; Respiratory - pharyngitis and dyspnea; Special senses - pain in the eye, conjunctivitis and retinal hemorrhage; Urogenital - dysuria.

There have been rare reports of gastrointestinal irritation and gastrointestinal bleeding with use of another drug in this non-deformable sustained release formulation, although causal relationship to the drug is uncertain.

The following are adverse experiences reported with immediate release glipizide and other sulfonylureas, but have not been observed with GLUCOTROL XL:

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

Metabolic: Hepatic porphyria and disulfiram-like reactions have been reported with sulfonylureas. In the mouse, glipizide pretreatment did not cause an accumulation of acetaldehyde after ethanol administration. Clinical experience to date has shown that glipizide has an extremely low incidence of disulfiram-like alcohol reactions.

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

OVERDOSAGE: *Overdosage can produce hypoglycemia. Mild hypoglycemic symptoms without loss of* consciousness or neurologic findings should be treated aggressively with oral glucose and adjustments in drug dosage and/or meal patterns. Close monitoring should continue until the physician is assured that the patient is out of danger. Severe hypoglycemic reactions with coma, seizure, or other neurological impairment occur infrequently, but constitute medical emergencies requiring immediate hospitalization. If hypoglycemic coma is diagnosed or suspected, the patient should be given 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 glipizide from plasma may be prolonged in persons with liver disease. Because of the extensive protein binding of glipizide, dialysis is unlikely to be of benefit.

DOSAGE AND ADMINISTRATION: There is no fixed dosage regimen for the management of diabetes mellitus with GLUCOTROL XL Extended Release Tablet or any other hypoglycemic agent. In general, GLUCOTROL XL should be given with breakfast.

Recommended Dosing: The recommended starting dose of GLUCOTROL XL is 5 mg per day, given with breakfast. The recommended dose for geriatric patients is also 5 mg per day.

Dosage adjustment should be based on laboratory measures of glycemic control. While fasting blood glucose levels generally reach steady state following initiation or change in GLUCOTROL XL dosage, a single fasting glucose determination may not accurately reflect the response to therapy. In most cases, hemoglobin A_{1c} level measured at three month intervals is the preferred means of monitoring response to therapy.

Hemoglobin A_{1c} should be measured as GLUCOTROL XL therapy is initiated at the 5 mg dose and repeated approximately three months later. If the result of this test suggests that glycemic control over the preceding three months was inadequate, the GLUCOTROL XL dose may be increased to 10 mg. Subsequent dosage adjustments should be made on the basis of hemoglobin A_{1c} levels measured at three month intervals. If no improvement is seen after three months of therapy with a higher dose, the previous dose should be resumed. Decisions which utilize fasting blood glucose to adjust GLUCOTROL XL therapy should be based on at least two or more similar, consecutive values obtained seven days or more after the previous dose adjustment.

Most patients will be controlled with 5 mg or 10 mg taken once daily. However, some patients may require up to the maximum recommended daily dose of 20 mg. While the glycemic control of selected patients may improve with doses which exceed 10 mg, clinical studies conducted to date have not demonstrated an additional group average reduction of hemoglobin A_{1c} beyond what was achieved with the 10 mg dose.

More detailed information available on request.

THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

VOLUME 18 NUMBER 6

Diabetes Care

Diabetes Care is a journal for the health-care practitioner that is intended to increase knowledge, stimulate research, and promote better management of people with diabetes mellitus. To achieve these goals, the journal publishes original articles on human studies in the areas of epidemiology, clinical trials, behavioral medicine, nutrition, education, health-care delivery, medical economics, and clinical care. The journal also publishes clinically relevant review articles, clinical observations, letters to the editor, and public health/medical news or points of view. Topics covered are of interest to clinically oriented physicians, researchers, epidemiologists, psychologists, diabetes educators, and other professionals.

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The mission of the American Diabetes Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

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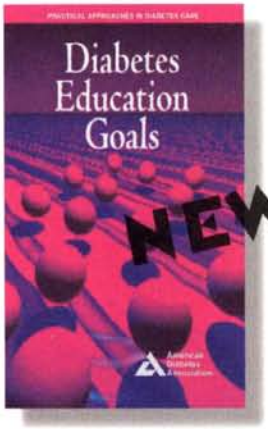

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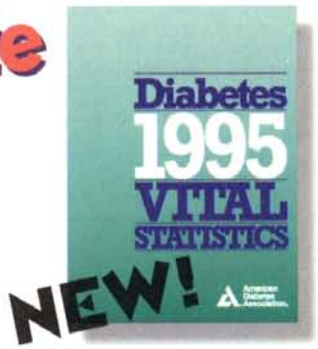

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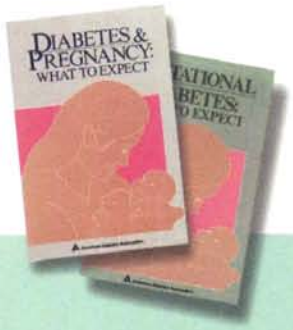

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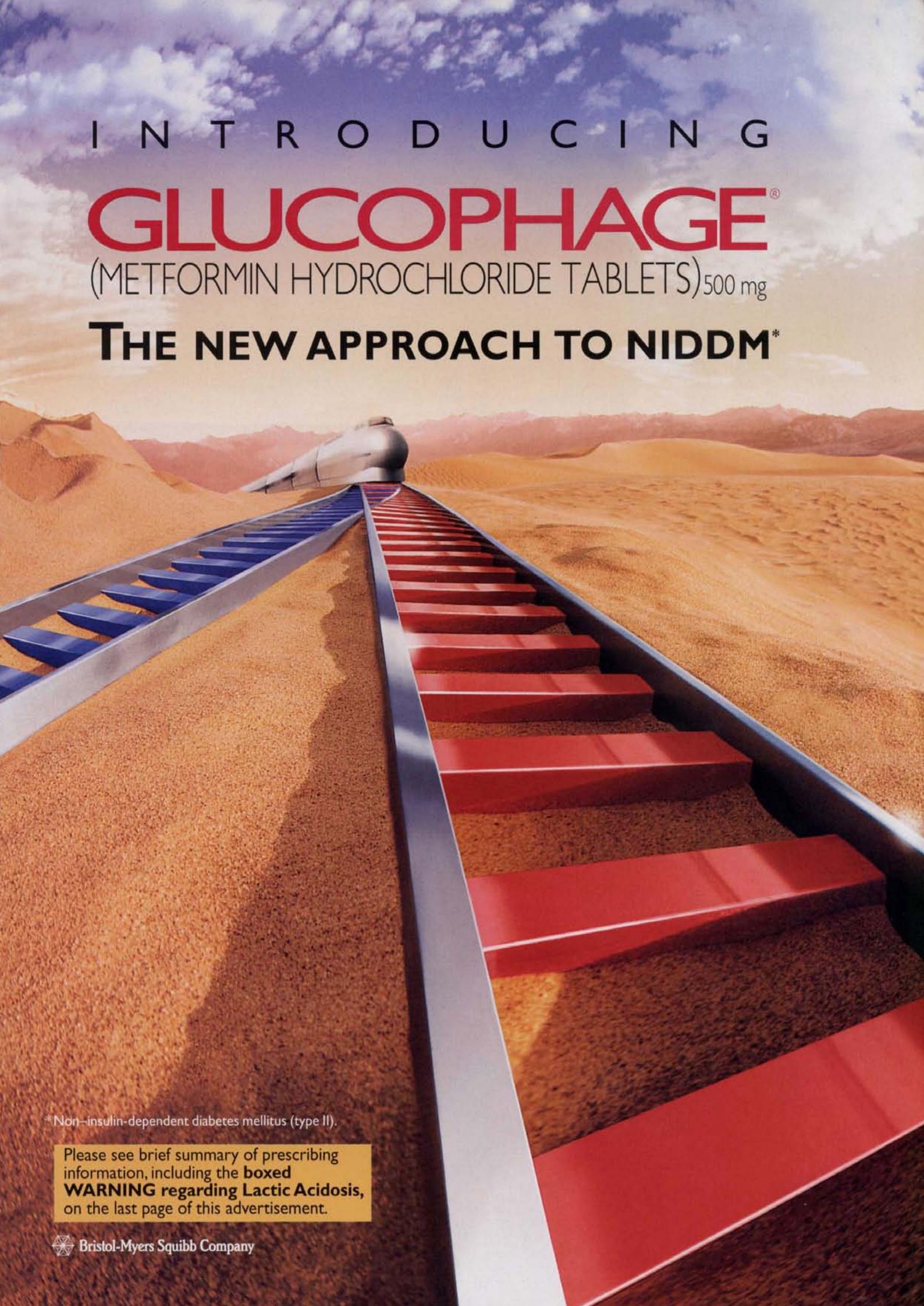
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*Non-insulin-dependent diabetes mellitus (type II).
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Bristol-Myers Squibb Company

THE NEW ***NON***-SULFONYLUREA APPROACH TO NIDDM

BYPASSES THE PANCREAS WITH

GLUCOPHAGE lowers blood glucose levels without stimulating insulin secretion.[1]

No effect on pancreatic beta cells or insulin secretion.[1]

Does not produce hypoglycemia.[1]

GLUCOPHAGE is highly effective first-line drug therapy.[2]

Significantly decreases fasting plasma glucose (FPG) when used as an adjunct to diet.[2]

Mean difference in FPG compared to placebo

GLUCOPHAGE vs placebo

P=0.001

-59 mg/dL

Study 1: Results of a double-blind, placebo-controlled, multicenter trial over 29 weeks. 286 randomized NIDDM patients: GLUCOPHAGE, n=141; placebo, n=145. Average dosage of GLUCOPHAGE was 1,980 mg/day.[2]

DIRECT ANTIHYPERGLYCEMIC ACTION.

GLUCOPHAGE is synergistic in combination.[2]

Combining GLUCOPHAGE and a sulfonylurea with diet lowers FPG significantly more than monotherapy.[2]

Mean difference in FPG compared to monotherapy

GLUCOPHAGE plus glyburide vs glyburide alone

P=0.001

Study 2: Results of a double-blind, placebo-controlled, parallel-group, multicenter trial comparing GLUCOPHAGE (n=210), glyburide (n=209), and the combination (n=213) over 29 weeks. 632 randomized NIDDM patients in whom glyburide monotherapy (20 mg/day) had failed to provide adequate control. Average dosage of GLUCOPHAGE was 2,050 mg/day as monotherapy and 1,894 mg/day in combination.[2]

GLUCOPHAGE produces modest improvements in key lipids.[1]

Significantly reduces total cholesterol, LDL cholesterol, and triglycerides ($P<0.05$), and has a neutral effect on HDL cholesterol.[1,2]

Improvement noted particularly when baseline lipid levels were elevated.[1]

GLUCOPHAGE can help NIDDM patients keep their weight under control while lowering blood glucose.[1]

In contrast to sulfonylureas, body weight of individuals on GLUCOPHAGE tends to remain stable or decrease.[1]

NEW

WITH DIET—ALONE OR WITH A SULFONYLUREA

GLUCOPHAGE®

(METFORMIN HYDROCHLORIDE TABLETS) 500 mg

THE NEW APPROACH TO NIDDM

Please see brief summary of prescribing information, including the **boxed WARNING regarding Lactic Acidosis,** on the last page of this advertisement.

THE NEW *NON*-SULFONYLUREA APPROACH TO NIDDM

PROVIDES ESTABLISHED SAFETY AND OFFERS BID DOSING.

Safety established in over 3 million patient-years of experience.[3]

Mild and transient GI side effects are most common.[1]

Diarrhea, nausea, vomiting, bloating, or flatulence may occur, especially during initiation of GLUCOPHAGE

- approximately 30% more frequent than with placebo[1]
- approximately 4% of patients discontinue therapy due to GI reactions.[1]

Rare occurrence of lactic acidosis, a serious condition.

Approximately 0.03 cases per 1,000 patient-years reported worldwide[1]

- if cases occur, up to half may be fatal
- seen primarily in patients with renal insufficiency
- Patient Package Insert lists symptoms to be discussed with patients.

The UGDP study suggested increased cardiovascular risk with oral antidiabetics.

Appropriate patient selection is key.[1]

Contraindicated in patients with renal disease or renal dysfunction and in patients with metabolic acidosis.

Temporarily withhold in patients receiving iodinated contrast materials for radiologic studies.

Avoid in patients with impaired hepatic function or excessive alcohol intake (acute or chronic).

Not recommended for children or pregnant women.

Recommended starting dosage: 500 mg bid with meals.[1]

Increase dosage by one 500 mg tablet each week.

Minimize GI reactions by slow titration and administration with food

- occasionally, temporary dose reduction may be useful.

Individualize dosage based on effectiveness and tolerance, up to a maximum of 2500 mg administered on a tid schedule.

NEW

WITH DIET—ALONE OR WITH A SULFONYLUREA

GLUCOPHAGE®

(METFORMIN HYDROCHLORIDE TABLETS) 500 mg

THE NEW APPROACH TO NIDDM

References: 1. GLUCOPHAGE Package Insert. **2.** Data on file, Bristol-Myers Squibb Company. **3.** Sirtori CR, Pasik C: Re-evaluation of a biguanide, metformin: mechanism of action and tolerability. *Pharmacol Res* 30(3):187-228, 1994.

Please see brief summary of prescribing information, including the **boxed WARNING regarding Lactic Acidosis,** on the last page of this advertisement.

GLUCOPHAGE® (METFORMIN HYDROCHLORIDE TABLETS) 500 mg

CONTRAINDICATIONS: GLUCOPHAGE is contraindicated in patients with: **1.** Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels ≥1.5 mg/dL [males], ≥1.4 mg/dL [females] or abnormal creatinine clearance) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia (see WARNINGS and PRECAUTIONS). **2.** GLUCOPHAGE should be temporarily withheld in patients undergoing radiologic studies involving parenteral administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function. (See also PRECAUTIONS). **3.** Known hypersensitivity to metformin hydrochloride. **4.** Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

WARNINGS: Lactic Acidosis: Lactic acidosis is a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with GLUCOPHAGE; when it occurs, it is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus, and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels (>5 mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When metformin is implicated as the cause of lactic acidosis, metformin plasma levels >5 µg/mL are generally found. The reported incidence of lactic acidosis in patients receiving metformin hydrochloride is very low (approximately 0.03 cases/1,000 patient-years, with approximately 0.015 fatal cases/1,000 patient-years). Reported cases have occurred primarily in diabetic patients with significant renal insufficiency, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications. The risk of lactic acidosis increases with the degree of renal dysfunction and the patient's age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking GLUCOPHAGE and by use of the minimum effective dose of GLUCOPHAGE. In addition, GLUCOPHAGE should be promptly withheld in the presence of any condition associated with hypoxemia or dehydration. Because impaired hepatic function may significantly limit the ability to clear lactate, GLUCOPHAGE should generally be avoided in patients with clinical or laboratory evidence of hepatic disease. Patients should be cautioned against excessive alcohol intake, either acute or chronic, when taking GLUCOPHAGE, since alcohol potentiates the effects of metformin hydrochloride on lactate metabolism. In addition, GLUCOPHAGE should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure (see also PRECAUTIONS). The onset of lactic acidosis often is subtle, and accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence and nonspecific abdominal distress. There may be associated hypothermia, hypotension and resistant bradyarrhythmias with more marked acidosis. The patient and the patient's physician must be aware of the possible importance of such symptoms and the patient should be instructed to notify the physician immediately if they occur (see also PRECAUTIONS). GLUCOPHAGE should be withdrawn until the situation is clarified. Serum electrolytes, ketones, blood glucose and, if indicated, blood pH, lactate levels and even blood metformin levels may be useful. Once a patient is stabilized on any dose level of GLUCOPHAGE, gastrointestinal symptoms, which are common during initiation of therapy, are unlikely to be drug related. Later occurrence of gastrointestinal symptoms could be due to lactic acidosis or other serious disease. Levels of fasting venous plasma lactate above the upper limit of normal but less than 5 mmol/L in patients taking GLUCOPHAGE do not necessarily indicate impending lactic acidosis and may be explainable by other mechanisms, such as poorly controlled diabetes or obesity, vigorous physical activity or technical problems in sample handling. (See also PRECAUTIONS.) Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonemia). Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking GLUCOPHAGE, the drug should be discontinued immediately and general supportive measures promptly instituted. Because metformin hydrochloride is dialyzable (with a clearance of up to 170 mL/min under good hemodynamic conditions), prompt hemodialysis is recommended to correct the acidosis and remove the accumulated metformin. Such management often results in prompt reversal of symptoms and recovery. (See also CONTRAINDICATIONS and PRECAUTIONS).

SPECIAL WARNING ON INCREASED RISK OF CARDIOVASCULAR MORTALITY: The administration of oral antidiabetic drugs has been reported to be associated with increased cardiovascular mortality as compared to treatment with diet alone or diet plus insulin.

PRECAUTIONS: General: ***Monitoring of renal function*** —GLUCOPHAGE is known to be substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Thus, patients with serum creatinine levels above the upper limit of normal for their age should not receive GLUCOPHAGE. In patients with advanced age, GLUCOPHAGE should be carefully titrated to establish the minimum dose for adequate glycemic effect, because aging is associated with reduced renal function. In elderly patients, renal function should be monitored regularly and, generally, GLUCOPHAGE should not be titrated to the maximum dose (see DOSAGE AND ADMINISTRATION). Before initiation of GLUCOPHAGE therapy and at least annually thereafter, renal function should be assessed and verified as normal. In patients in whom development of renal dysfunction is anticipated, renal function should be assessed more frequently and GLUCOPHAGE discontinued if evidence of renal impairment is present. — ***Use of concomitant medications that may affect renal function or metformin disposition*** —Concomitant medication(s) that may affect renal function or result in significant hemodynamic change or may interfere with the disposition of GLUCOPHAGE, such as cationic drugs that are eliminated by renal tubular secretion (See Drug Interactions), should be used with caution. — ***Radiologic studies involving the use of iodinated contrast materials (for example, intravenous urogram, intravenous cholangiography, angiography, and scans with contrast materials)*** —Parenteral contrast studies with iodinated materials can lead to acute renal failure and have been associated with lactic acidosis in patients receiving GLUCOPHAGE (see CONTRAINDICATIONS). Therefore, in patients in whom any such study is planned, GLUCOPHAGE should be withheld for at least 48 hours prior to, and 48 hours subsequent to, the procedure and reinstituted only after renal function has been re-evaluated and found to be normal. — ***Hypoxic states*** — Cardiovascular collapse (shock) from whatever cause, acute congestive heart failure, acute myocardial infarction and other conditions characterized by hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients on GLUCOPHAGE therapy, the drug should be promptly discontinued. — ***Surgical procedures*** —GLUCOPHAGE therapy should be temporarily suspended for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal. — ***Alcohol intake*** —Alcohol is known to potentiate the effect of metformin on lactate metabolism. Patients, therefore, should be warned against excessive alcohol intake, acute or chronic, while receiving GLUCOPHAGE. — ***Impaired hepatic function*** —Since impaired hepatic function has been associated with some cases of lactic acidosis, GLUCOPHAGE should generally be avoided in patients with clinical or laboratory evidence of hepatic disease. — ***Vitamin B_{12} levels*** — A decrease to subnormal levels of previously normal serum vitamin B_{12} levels, without clinical manifestations, is observed in approximately 7% of patients receiving GLUCOPHAGE in controlled clinical trials of 29 weeks duration. Such decrease, possibly due to interference with B_{12} absorption from the B_{12}-intrinsic factor complex, is, however, very rarely associated with anemia and appears to be rapidly reversible with discontinuation of GLUCOPHAGE or vitamin B_{12} supplementation. Measurement of hematologic parameters on an annual basis is advised in patients on GLUCOPHAGE and any apparent abnormalities should be appropriately investigated and managed (see Laboratory Tests). Certain individuals (those with inadequate vitamin B_{12} or calcium intake or absorption) appear to be predisposed to developing subnormal vitamin B_{12} levels. In these patients, routine serum vitamin B_{12} measurements at two- to three-year intervals may be useful. — ***Change in clinical status of previously controlled diabetic*** — A diabetic patient previously well controlled on GLUCOPHAGE who develops laboratory abnormalities or clinical illness (especially vague and poorly defined illness) should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. Evaluation should include serum electrolytes and ketones, blood glucose and, if indicated, blood pH, lactate, pyruvate and metformin levels. If acidosis of either form occurs, GLUCOPHAGE must be stopped immediately and other appropriate corrective measures initiated (see also WARNINGS). — ***Hypoglycemia*** — Hypoglycemia does not occur in patients receiving GLUCOPHAGE alone under usual circumstances of use, but could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitant use with other glucose-lowering agents (such as sulfonylureas) or ethanol. Elderly, debilitated or malnourished patients, and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects. Hypoglycemia may be difficult to recognize in the elderly, and in people who are taking beta-adrenergic blocking drugs. — ***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 temporary loss of glycemic control may occur. At such times, it may be necessary to withhold GLUCOPHAGE and temporarily administer insulin. GLUCOPHAGE may be reinstituted after the acute episode is resolved. The effectiveness of oral antidiabetic drugs in lowering blood glucose to a targeted level decreases in many patients over a period of time. This phenomenon, which may be due to progression of the underlying disease or to diminished responsiveness to the drug, is known as secondary failure, to distinguish it from primary failure in which the drug is ineffective during initial therapy. Should secondary failure occur with GLUCOPHAGE or sulfonylurea monotherapy, combined therapy with GLUCOPHAGE and sulfonylurea may result in a response. Should secondary failure occur with combined GLUCOPHAGE/sulfonylurea therapy, it may be necessary to initiate insulin therapy. — **Information for Patients:** Patients should be informed of the potential risks and advantages of GLUCOPHAGE and of alternative modes of therapy. They should also be informed about the importance of adherence to dietary instructions, of a regular exercise program, and of regular testing of blood glucose, glycosylated hemoglobin, renal function and hematologic parameters. The risks of lactic acidosis, its symptoms, and conditions that predispose to its development, as noted in the WARNINGS and PRECAUTIONS sections should be explained to patients. Patients should be advised to discontinue GLUCOPHAGE (metformin hydrochloride tablets) immediately and to promptly notify their health practitioner if unexplained hyperventilation, myalgia, malaise, unusual somnolence or other nonspecific symptoms occur. Once a patient is stabilized on any dose level of GLUCOPHAGE, gastrointestinal symptoms, which are common during initiation of therapy, are unlikely to be drug related. Later occurrence of gastrointestinal symptoms could be due to lactic acidosis or other serious disease. Patients should be counselled against excessive alcohol intake, either acute or chronic, while receiving GLUCOPHAGE. GLUCOPHAGE alone does not usually cause hypoglycemia, although it may occur when GLUCOPHAGE is used in conjunction with oral sulfonylureas. When initiating combination therapy, the risks of hypoglycemia, its symptoms and treatment, and conditions that predispose to its development should be explained to patients. (See Patient Package Insert.) — **Laboratory Tests:** Response to all diabetic therapies should be monitored by periodic measurements of fasting blood glucose and glycosylated hemoglobin levels, with a goal of decreasing these levels toward the normal range. During initial dose titration, fasting glucose can be used to determine the therapeutic response. Thereafter, both glucose and glycosylated hemoglobin should be monitored. Measurements of glycosylated hemoglobin may be especially useful for evaluating long-term control (see also DOSAGE AND ADMINISTRATION). Initial and periodic monitoring of hematologic parameters (e.g., hemoglobin/hematocrit and red blood cell indices) and renal function (serum creatinine) should be performed, at least on an annual basis. While megaloblastic anemia has rarely been seen with GLUCOPHAGE therapy, if this is suspected, vitamin B_{12} deficiency should be excluded. — **Drug Interactions:** ***Glyburide*** — In a single-dose interaction study in NIDDM subjects, co-administration of metformin and glyburide did not result in any changes in either metformin pharmacokinetics or pharmacodynamics. Decreases in glyburide AUC and C_{max} were observed, but were highly variable. The single-dose nature of this study and the lack of correlation between glyburide blood levels and pharmacodynamic effects, makes the clinical significance of this interaction uncertain (see DOSAGE AND ADMINISTRATION, Concomitant Glucophage and Oral Sulfonylurea Therapy). — ***Furosemide*** —A single-dose, metformin-furosemide drug interaction study in healthy subjects demonstrated that pharmacokinetic parameters of both compounds were affected by co-administration. Furosemide increased the metformin plasma and blood C_{max} by 22% and blood AUC by 15%, without any significant change in metformin renal clearance. When administered with metformin, the C_{max} and AUC of furosemide were 31% and 12% smaller, respectively, than when administered alone, and the terminal half-life was decreased by 32%, without any significant change in furosemide renal clearance. No information is available about the interaction of metformin and furosemide when co-administered chronically. — ***Nifedipine*** —A single-dose, metformin-nifedipine drug interaction study in normal healthy volunteers demonstrated that co-administration of nifedipine increased plasma metformin C_{max} and AUC by 20% and 9%, respectively, and increased the amount excreted in the urine. T_{max} and half-life were unaffected. Nifedipine appears to enhance the absorption of metformin. Metformin had minimal effects on nifedipine. — ***Cationic drugs*** —Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, and vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems. Such interaction between metformin and oral cimetidine has been observed in normal healthy volunteers in both single- and multiple-dose, metformin-cimetidine drug interaction studies, with a 60% increase in peak metformin plasma and whole blood concentrations and a 40% increase in plasma and whole blood metformin AUC. There was no change in elimination half-life in the single-dose study. Metformin had no effect on cimetidine pharmacokinetics. Although such interactions remain theoretical (except for cimetidine), careful patient monitoring and dose adjustment of GLUCOPHAGE and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system. — ***Other*** — Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include thiazide 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 GLUCOPHAGE, the patient should be closely observed to maintain adequate glycemic control. In healthy volunteers, the pharmacokinetics of metformin and propranolol and metformin and ibuprofen were not affected when co-administered in single-dose interaction studies. Metformin is negligibly bound to plasma proteins and is, therefore, less likely to interact with highly protein-bound drugs such as salicylates, sulfonamides, chloramphenicol, and probenecid, as compared to the sulfonylureas, which are extensively bound to serum proteins. — **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term carcinogenicity studies have been performed in rats (dosing duration of 104 weeks) and mice (dosing duration of 91 weeks) at doses up to and including 900 mg/kg/day and 1500 mg/kg/day, respectively. These doses are both approximately three times the maximum recommended human daily dose on a body surface area basis. No evidence of carcinogenicity with metformin was found in either male or female mice. Similarly, there was no tumorigenic potential observed with metformin in male rats. However, an increased incidence of benign stromal uterine polyps was seen in female rats treated with 900 mg/kg/day. No evidence of a mutagenic potential of metformin was found in the Ames test (*S. typhimurium*), gene mutation test (mouse lymphoma cells), chromosomal aberrations test (human lymphocytes), or *in-vivo* micronuclei formation test (mouse bone marrow). Fertility of male or female rats was unaffected by metformin administration at doses as high as 600 mg/kg/day, or approximately two times the maximum recommended human daily dose on a body surface area basis. — **Pregnancy:** ***Teratogenic effects — Pregnancy Category B.*** Safety in pregnant women has not been established. Metformin was not teratogenic in rats and rabbits at doses up to 600 mg/kg/day, or about two times the maximum recommended human daily dose on a body surface area basis. Determination of fetal concentrations demonstrated a partial placental barrier to metformin. Because animal reproduction studies are not always predictive of human response, any decision to use this drug should be balanced against the benefits and risks. Because recent information suggests that abnormal blood glucose levels during pregnancy are associated with a higher incidence of congenital abnormalities, there is a consensus among experts that insulin be used during pregnancy to maintain blood glucose levels as close to normal as possible. — **Nursing Mothers:** Studies in lactating rats show that metformin is excreted into milk and reaches levels comparable to those in plasma. Similar studies have not been conducted in nursing mothers, but caution should be exercised in such patients, and a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. — **Pediatric Use:** Safety and effectiveness in children have not been established. Studies in maturity-onset diabetes of the young (MODY) have not been conducted. — **Geriatric Use:** Controlled clinical studies of GLUCOPHAGE did not include sufficient numbers of elderly patients to determine whether they respond differently from younger patients, although other reported clinical experience has not identified differences in responses between the elderly and younger patients. GLUCOPHAGE is known to be substantially excreted by the kidney and because the risk of serious adverse reactions to the drug is greater in patients with impaired renal function, it should only be used in patients with normal renal function (see CONTRAINDICATIONS, CLINICAL PHARMACOLOGY, Pharmacokinetics). Because aging is associated with reduced renal function, GLUCOPHAGE should be used with caution as age increases. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function. Generally, elderly patients should not be titrated to the maximum dose of GLUCOPHAGE (see also DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS: Lactic Acidosis: See WARNINGS, PRECAUTIONS and OVERDOSAGE Sections. — **Gastrointestinal Reactions:** Gastrointestinal symptoms (diarrhea, nausea, vomiting, abdominal bloating, flatulence, and anorexia) are the most common reactions to GLUCOPHAGE and are approximately 30% more frequent in patients on GLUCOPHAGE monotherapy than in placebo-treated patients, particularly during initiation of GLUCOPHAGE therapy. These symptoms are generally transient and resolve spontaneously during continued treatment. Occasionally, temporary dose reduction may be useful. In controlled trials, GLUCOPHAGE was discontinued due to gastrointestinal reactions in approximately 4% of patients. Because gastrointestinal symptoms during therapy initiation appear to be dose-related, they may be decreased by gradual dose escalation and by having patients take GLUCOPHAGE with meals (see DOSAGE AND ADMINISTRATION). Because significant diarrhea and/or vomiting may cause dehydration and prerenal azotemia, under such circumstances, GLUCOPHAGE should be temporarily discontinued. For patients who have been stabilized on GLUCOPHAGE, nonspecific gastrointestinal symptoms should not be attributed to therapy unless intercurrent illness or lactic acidosis have been excluded. — **Special Senses:** During initiation of GLUCOPHAGE therapy, approximately 3% of patients may complain of an unpleasant or metallic taste, which usually resolves spontaneously. — **Dermatologic Reactions:** The incidence of rash/dermatitis in controlled clinical trials was comparable to placebo for GLUCOPHAGE monotherapy and to sulfonylurea for GLUCOPHAGE/sulfonylurea therapy. — **Hematologic:** (See also PRECAUTIONS). During controlled clinical trials of 29 weeks duration, approximately 9% of patients on GLUCOPHAGE monotherapy and 6% of patients on GLUCOPHAGE/sulfonylurea therapy developed asymptomatic subnormal serum vitamin B_{12} levels; serum folic acid levels did not decrease significantly. However, only five cases of megaloblastic anemia have been reported with metformin administration (none during U.S. clinical studies) and no increased incidence of neuropathy has been observed. Therefore, serum B_{12} levels should be appropriately monitored or periodic parenteral B_{12} supplementation considered.

OVERDOSAGE: Hypoglycemia has not been seen even with ingestion of up to 85 grams of GLUCOPHAGE, although lactic acidosis has occurred in such circumstances (see WARNINGS). Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom metformin overdosage is suspected.

Consult package insert before prescribing GLUCOPHAGE (metformin hydrochloride tablets). F5-B001A 1/95

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MEDWatch 1-800-332-1088 available to report serious adverse events for any drug.

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The American Diabetes Association wishes to acknowledge

the following individuals who have served as volunteer reviewers for the Recognition Program in the past year. ADA Recognition has become the foremost quality assurance mechanism in the nation for diabetes patient education programs. The time and expertise of these reviewers in support of the Recognition Program is greatly appreciated.

American Diabetes Association®

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Notice to Readers

The *Clinical Practice Recommendations 1995* (January supplement to *Diabetes Care*) inadvertently omitted three articles that should be considered part of the American Diabetes Association recommendations to health care practitioners. They are:

Position Statement

Implications of the Diabetes Control and Complications Trial
Diabetes Care, vol. 16, pages 1517-1520, November 1993

Consensus Statements

Treatment of Hypertension in Diabetes
Diabetes Care, vol. 16, pages 1394-1401, October 1993

Diagnosis and Management of Nephropathy in Patients with Diabetes Mellitus
Diabetes Care, vol. 17, pages 1357-1361, November 1994

These articles will be included in the *Clinical Practice Recommendations 1996*

CALL FOR EDITORS
DIABETES AND *DIABETES CARE*

The American Diabetes Association is seeking letters of interest in the editorship of the journals *Diabetes* and *Diabetes Care*.

The appointment is for three years, with a possible two-year extension. Editorship requires the availability of at least two Associate Editors located in the same city, preferably the same institution. The new editors of both journals will begin their tenure in January 1997, following a transition period (wherein all new submissions to the journal will be directed to the new editorial team for review) beginning in the Summer of 1996.

Diabetes Care is a journal for the health care practitioner that is intended to increase knowledge, stimulate research, and promote better management of people with diabetes mellitus. To achieve these goals, the journal publishes original articles on human studies in the areas of epidemiology, clinical trials, behavioral medicine, nutrition, education, health care delivery, medical economics, and clinical care. The journal also publishes clinically relevant review articles, clinical observations, letters to the editor, and public health/medical news or points of view. 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 pathological 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.

Interested parties must submit a letter of interest by July 1, 1995. Curriculum vitae of the applicants for Editor and Associate Editors should be included. Please address correspondence to:

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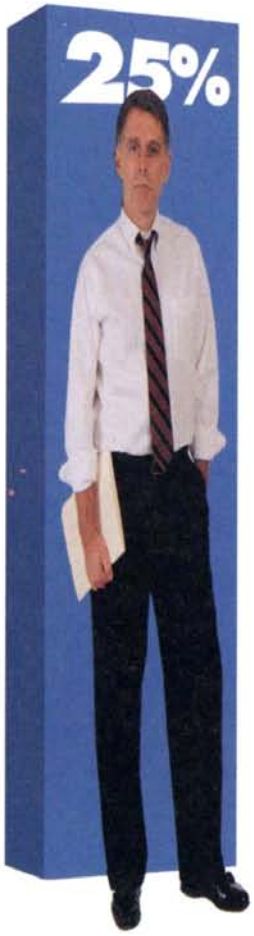
How Likely Are Your Patients To Be Magnesium Deficient?

CHF patients



Diabetics

Hypertensives

Here's The Long And The Short Of It.

Mg deficiency may be the most underappreciated and underdiagnosed electrolyte irregularity in medical practice today.[1] An American Diabetes Association (ADA) consensus report found Mg levels reduced in disease states such as hypertension, diabetes, cardiac arrhythmias and congestive heart failure (CHF).[2]

25% of diabetics and many CHF and hypertension sufferers are at risk of Mg deficiency.[3]

Clinical studies have shown one out of four people with diabetes have a magnesium deficiency[3] and they've revealed that low levels of Mg are associated with insulin resistance.[4-5] Also, Mg deficiency was found in 19% of CHF patients in an epidemiological study. Mg-deficient patients had a significantly higher frequency of ventricular tachycardia (VT) and significantly worse prognoses than CHF patients with normal serum Mg levels.[6] And substantial experimental evidence has been reported in *The American Journal Of Cardiology* and elsewhere showing that dietary Mg deficiency increases arterial contractility, while elevating Mg decreases blood pressure.[7-11]

Mg-deficient CHF patients had 4 times as many arrhythmias.[6]

Patients treated with loop or thiazide diuretics should be routinely screened for hypomagnesemia because of the possibility of arrhythmias and ECG abnormalities.[1]

Specify the only supplement that is magnesium chloride.

The ADA consensus report recommends that diabetic patients with documented hypomagnesemia receive an oral magnesium chloride supplement of dependable bioavailability and potency.[2] Other Mg supplements are relatively insoluble and may provide substantially less free Mg for absorption.[12] SLOW-MAG® is the only patented Mg chloride dietary supplement and is enteric coated to reduce the frequency of GI side effects.

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1. Whang R. Magnesium deficiency: pathogenesis, prevalence, and clinical implications. *Am J Med.* 1987;82 (suppl 3A):24-29. 2. American Diabetes Association. Magnesium supplementation in the treatment of diabetes. *Diabetes Care.* 1992;15:1065-1067. 3. Mather HM, Nisbet JA, Burton GH, et al. Hypomagnesaemia in diabetes. *Clinica Chimica Acta.* 1979;95:235-242. 4. Yajnik CS, Smith RF, Hockaday TDR, et al. Fasting plasma magnesium concentrations and glucose disposal in diabetes. *BMJ.* 1984;288:1032-1034. 5. Resnick LM, Gupta RK, Gruenspan H, et al. Hypertension and peripheral insulin resistance: possible mediating role of intracellular free magnesium. *Am J Hypertens.* 1990;3:373-379. 6. Gottlieb SS, Baruch L, Kukin ML, et al. Prognostic importance of the serum magnesium concentration in patients with congestive heart failure. *J Am Coll Cardiol.* 1990;16:827-831. 7. Seelig MS. *Magnesium Deficiency in the Pathogenesis of Disease: Early Roots of Cardiovascular, Skeletal, and Renal Abnormalities.* New York, NY: Plenum Pub Corp. 1980. 8. Altura BM, Altura BT. New perspectives on the role of magnesium in the pathophysiology of the cardiovascular system: I. Clinical aspects. *Magnesium.* 1985;4:226-244. 9. Haddy FJ, Seelig MS. Magnesium and the arteries: II. Physiologic effects of electrolyte abnormalities on arterial resistance. In: Cantin M, Seelig MS, eds. *Magnesium in Health and Disease.* New York, NY: SP Med & Sci Books. 1980:639-657. 10. Altura BM, Altura BT. Interactions of Mg and K on blood vessels --aspects in view of hypertension: review of present status and new findings. *Magnesium.* 1984;3;175-194. 11. Altura BM, Altura BT. Role of magnesium ions in contractility of blood vessels and skeletal muscles. *Magnesium Bull.* 1981;1a:102-114. 12. Classen HG, Marquardt P, Spath M, et al. Improvement by chlorine of the intestinal absorption of inorganic and organic Mg compounds and of their protective effect against adrenergic cardiopathy. In: Fleckenstein A, Rona G, eds. *Recent Advances in Studies on Cardiac Structure and Metabolism.* Vol. 6. Baltimore, Md: University Park Press; 1975:111-119.

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Diabetic Medicine

Journal of the British Diabetic Association

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THE ROLE OF THE GI TRACT IN NIDDM

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Chief, Endocrinology and Metabolism/Diabetes
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The Incretin Hypothesis Revisited
Burkhard Göke, MD
Professor of Molecular Endocrinology
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Dietary Management of NIDDM:
Current Concepts and Controversies
Robert Josse, MD
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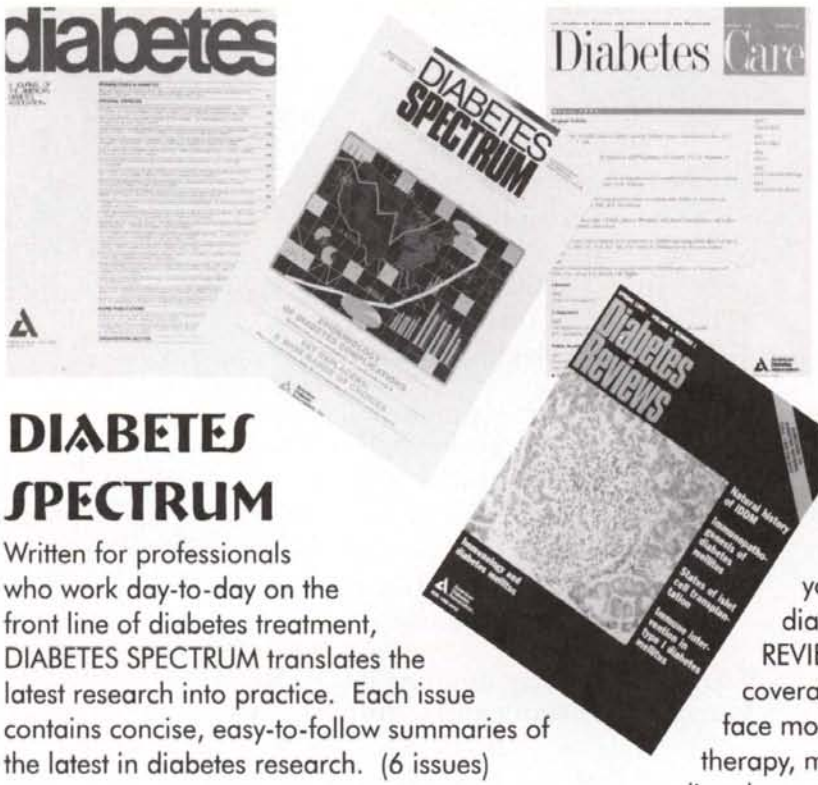

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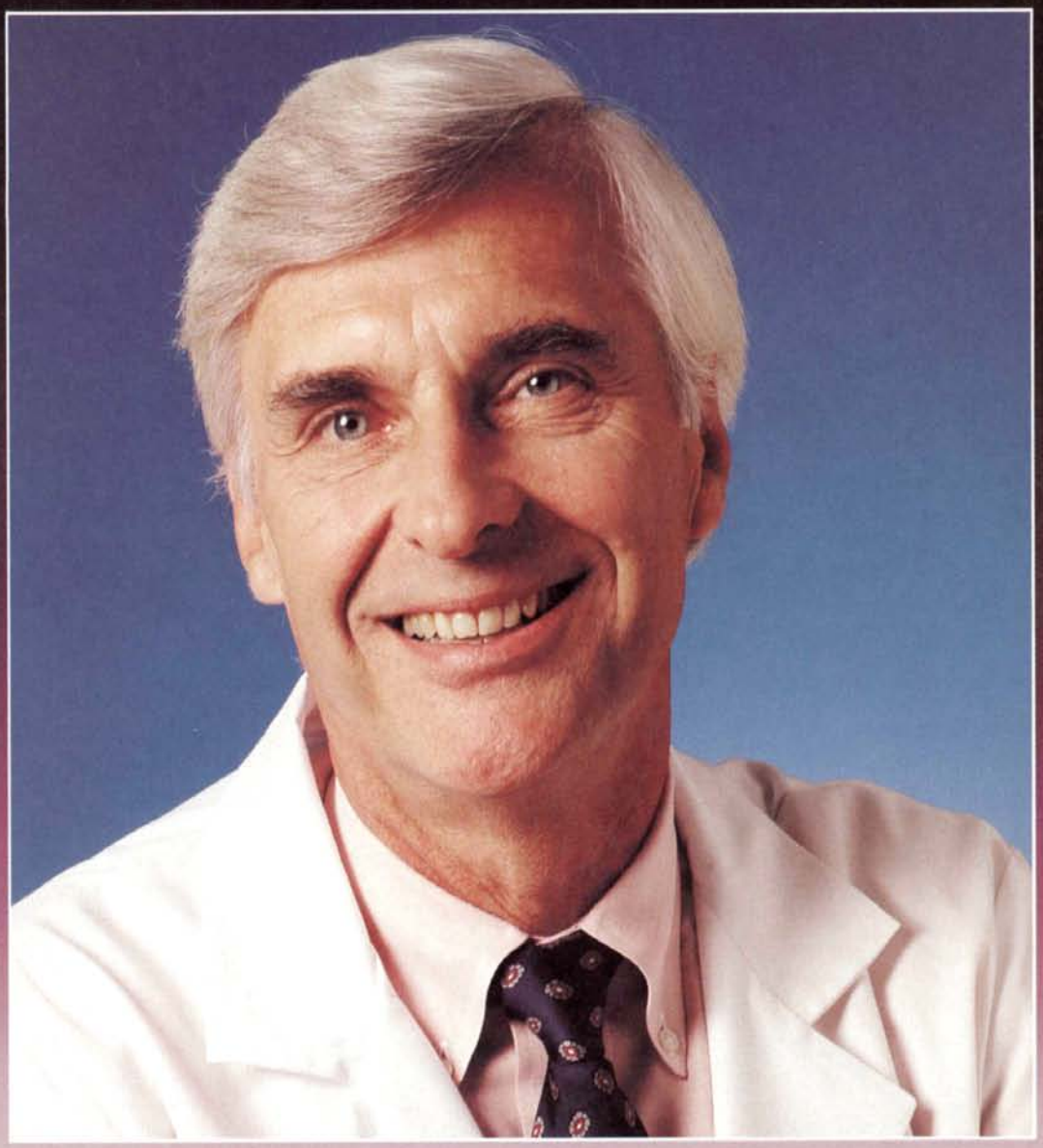

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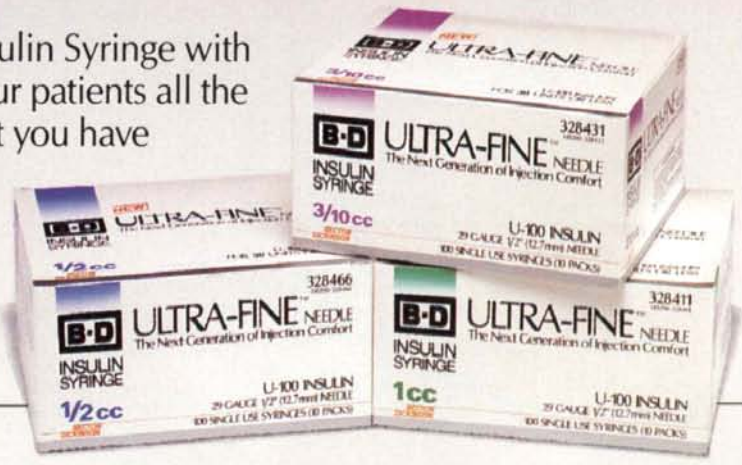

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ATLANTA 1995

55TH ANNUAL MEETING & SCIENTIFIC SESSIONS

AMERICAN DIABETES ASSOCIATION 55TH ANNUAL MEETING AND SCIENTIFIC SESSIONS

SATURDAY, JUNE 10

Morning
Registration Open
Concurrent Symposia
(8:00 am – 10:00 am)
- Fuel Flux in Exercise
- Type I Diabetes Prevention Trials
- Modulating Autoimmunity

Concurrent Symposia
(10:00 am – 12:00 pm)
- Providing Care for Patients in a Changing Health-Care Environment
- Novel Pharmacological Therapies and Prevention of NIDDM
- Molecular Basis of Obesity

Afternoon
General Poster Session
Exhibits Open
Concurrent Sessions
- Current Controversy
- Meet-the-Professor Session
- Oral Abstract Presentations
- Workshops (3)
  - Intensive Insulin Therapy: Initiation, Special Problems, Pump
- Special Interest Groups

SUNDAY, JUNE 11

Morning
Registration Open
Exhibits Open
Concurrent Symposia
- Current Education Issues
- Diabetic Neuropathy and the Foot
- Genetics of Diabetes

President's Address
Banting Lecture

Afternoon
General Poster Session
Exhibits Open
Concurrent Sessions
- Current Controversy
- Oral Abstract Presentations
- Workshops
  - Foot Care
  - American Diabetes Association/American Dietetic Association's Five Nutrition Tools
- Special Interest Groups
- State-of-the-Art Lecture

Evening
President's Poster Session

MONDAY, JUNE 12

Morning
Registration Open
Exhibits Open
Concurrent Sessions
- Oral Abstract Presentations
- Workshops
  - How to Design A Comprehensive Diabetes Education Program to Meet the Standards
  - Treatment of Dyslipidemia with Diabetes
- Meet-the-Professor Session
- Special Interest Groups
- State-of-the-Art Lecture

Scientific Achievement Awards Presentation
Lilly Lecture

Afternoon
General Poster Session
Exhibit Hall Open
Concurrent Sessions
- Current Controversy
- Oral Abstract Presentations
- Workshops
  - Hypoglycemia/Blood Glucose Awareness Training
  - Overcoming Behavioral Barriers to Intensive Treatment
- Special Interest Groups
- Poster Discussion Sessions

NEW SESSIONS!

CURRENT CONTROVERSY *and* **MEET-THE-PROFESSOR** Sessions
New this year are two small group interactive learning sessions—*Current Controversy* and *Meet-the-Professor*.

The *Current Controversy* sessions will focus on a presentation of two opposing points of view on a controversial issue, followed by a moderated discussion. This educational, interactive session will provide attendees with an opportunity to reflect on the issues presented and to formulate an informed opinion. *Meet-the-Professor* sessions provide an opportunity for attendees to meet with leading experts in an informal setting to discuss selected topics.

SPECIAL INTEREST GROUPS

Join your colleagues for an informal networking opportunity to discuss a subject or area of mutual interest during the Special Interest Group meetings scheduled throughout the Scientific Sessions. These groups/subjects will include, among others: Nurse Practitioners, Dietitians, DCCT Trial Coordinators, Young Investigators, Genetics of NIDDM. You do not need to register for these meetings.
A complete list will be available in the Advance Program.

JUNE 10-13, 1995
ATLANTA, GEORGIA

EXCITING NEW PROGRAM FORMAT

Join us in Atlanta for the 55th Scientific Sessions! Beginning on Saturday, June 10, and ending by noon on Tuesday, June 13, each day is filled with the latest information in diabetes research and clinical care presented through concurrent symposia, poster presentations, and multiple concurrent small group learning and exchange sessions. ***Call now for registration information,*** and join your colleagues for this outstanding educational opportunity.

TUESDAY, JUNE 13

Morning
Registration Open
Concurrent Symposia
- Behavioral Medicine Interventions: Implementation and Reimbursement
- Epidemiology and Prevention of Diabetic Nephropathy
- Pathogenesis and Prevention of Diabetic Embryopathy
- Islet Metabolism and Glucose Desensitization

Concurrent Sessions
- Oral Abstract Presentations
- Workshops
  - Nutrition Practice Guidelines
  - Treatment of NIDDM: Potential New Pharmacologic Therapies
- Special Interest Groups
- Kelly West Lecture
- State-of-the-Art Lecture

New Event

DIABETES EDUCATION PROGRAM POSTERS

Join us for a new session this year for health care educators. A special poster session will be presented during the 1995 Scientific Sessions focusing on the presentation of information on programs, tools, and resources of successful, innovative diabetes education programs.

Take this opportunity to share program ideas with your colleagues. For more information and a submission application contact: American Diabetes Association, Professional Education Dept., 1660 Duke Street, Alexandria, VA 22314, phone: 703/549-1500, ext. 212 or ext. 281.

MEETING THE NATIONAL STANDARDS FOR DIABETES SELF-MANAGEMENT EDUCATION PROGRAMS AND APPLYING FOR ADA RECOGNITION CONFERENCE

A Recognition Conference will be offered in conjunction with the American Diabetes Association's 55th Annual Meeting and Scientific Sessions. This one-day conference, "Meeting the National Standards for Diabetes Self-Management Education Programs and Applying for ADA Recognition" will be held Friday, June 9, 1995, at the Marriott Marquis Hotel preceding the Scientific Sessions. This intensive, practical program is designed for individuals who are interested in the process of completing an application for Recognition or are planning to submit an application within the next twelve months. CEU's will be awarded and enrollment is limited.

The registration fee for the Recognition Conference is $125.00. Further information about registration is available ***only*** from the Recognition Program at the American Diabetes Association's National Center, at 800-232-3472, ext. 403 or 214.

Please note: The new revised National Standards will be addressed at this conference.

FOR REGISTRATION INFORMATION CONTACT:

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ACT NOW!

ATLANTA

This year's host city for the 55th Annual Meeting and Scientific Sessions is diverse and cultural Atlanta, Georgia. Filled with a wealth of historical, educational, and recreational activities, Atlanta provides visitors with a well-rounded experience. Culture and history buffs will want to explore the African-American art display or the Atlanta Historical Society, both located downtown in restored historic buildings. In addition, the Atlanta Cyclorama in Grant Park offers a unique three-dimensional, sight-and-sound experience of the 1864 Civil War Battle of Atlanta.

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Tapes ordered by mail after meeting are $11.00 each.

FRIDAY - January 20, 1995

GENERAL SESSION - PATHOGENESIS

☐ APC95-1 **Pathogenesis of Immune Destruction of the Pancreatic B-cell: Do We Know How This Happens?**, *Alex Rabinovitch, MD*

☐ APC95-2 **What Causes NIDDM: Defects in Insulin Secretion, Insulin Action, or Both?**, *Simeon Taylor, MD, PhD*

☐ APC95-3 **Diabetic Neuropathy: Is It A Metabolic or A Vascular Disease?**, *Phillip A. Low, MD*

☐ APC95-4 **Atherosclerotic Vascular Disease: Does the Pathogenesis Differ in IDDM and NIDDM?**, *Christopher J. Fielding, PhD*

☐ APC95-5 **What Causes Hypoglycemic Unawareness?**, *Harry Shamoon, MD*

GENERAL SESSION - TOPICS IN ENDOCRINOLOGY

☐ APC95-6 **Endocrine Hypertension Diagnosis and Treatment**, *James R. Sowers, MD*

☐ APC95-7 **Hypoglycemic Disorders**, *F. John Service, MD, PhD*

☐ APC95-8 **Evaluation of Pituitary Tumors**, *Charles Abboud, MD*

☐ APC95-9 **Growth Hormone Deficiency in Children and Adolescents: Challenges in Diagnosis and Treatment**, *Alan D. Rogol, MD, PhD*

SPECIAL PRESENTATION

☐ APC95-10 **Revised Standards for Diabetes Patient Education Programs**, *Linda Haas, PhD, RN, CDE*

SATURDAY - January 21, 1995

GENERAL SESSION - TREATMENT

☐ APC95-11 **Can Complications in NIDDM be Prevented? If So, How?**, *Saul M. Genuth, MD*

☐ APC95-12 **Neuropathy: How Effective is the Treatment of Neuropathic Pain?**, *John Griffin, MD*

☐ APC95-13 **Nephropathy: Proven vs. Promising Therapies: Which is Which?**, Michael W. Steffes, MD, PhD

☐ APC95-14 **Atherosclerotic Vascular Disease: Does Treatment of Diabetic Dyslipidemia Differ Between IDDM and NIDDM?**, *M. James Howard, MD*

☐ APC95-15 **Obesity: Can It Be Treated Effectively? What Is the Definition of Effective?**, *Marion Franz, MS, RD, CDE*

CONCURRENT WORKSHOPS

☐ APC95-16 **Management of Intensive Insulin Therapy in the Private Practice Setting**, *Daniel L. Lorber, MD, CDE and Deborah Lagana, MSN, RD, CDE*

☐ APC95-17 **Economics of Diabetes: Is Intensive Management Cost-Effective? And If So, How Do You Convince Third-Party Payers?**, *Christine T. Tobin, RN, MBA, CDE and William H. Herman, MD*

☐ APC95-18 **Pancreas Transplantation: What It Can't Do, What It Can Do, and What It Might Be Able to Do**, *R. Paul Robertson, MD*

☐ APC95-19 **Diabetes Management: How to Be a More Culturally Sensitive Practitioner**, *Sharon Johnson, RN, CDE*

☐ APC95-20 **The Intelligent Use of Carbohydrates: Is the Ban on Sugar Lifted?**, *Sandra Gillespie, MMSc, RD/LD, CDE*

☐ APC95-21 **1994 Nutrition Recommendations: Theory to Practice**, *Melinda D. Maryniuk, MEd, RD, CDE*

SUNDAY - January 22, 1995

GENERAL SESSION - PREVENTION/EDUCATION

☐ APC95-22 **Prevention of IDDM: Is It Possible?**, *Jerry Palmer, MD*

☐ APC95-23 **Should People Be Screened for Diabetes? If So, Will It Alter the Outcome?**, *Mayer B. Davidson, MD*

☐ APC95-24 **Can Antioxidants Prevent Atherosclerotic Disease?**, *Alan Chait, MD*

☐ APC95-25 **Diabetic Foot Disease: How Do You Screen, and Can It Be Prevented?**, *Andrew J.M. Boulton, MD*

☐ APC95-26 **If Changing Behavior Prevents Disease, Can Behavior Be Changed?**, *David G. Schlundt, PhD*

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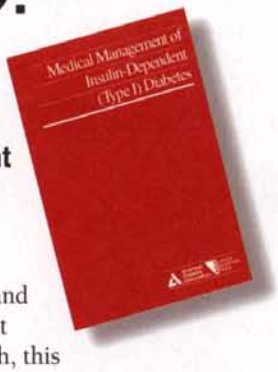

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Takes the latest research and clinical findings and turns it into a practical reference on managing type II diabetes.You'll get all the tools you need to diagnose and treat NIDDM and other forms of glucose intolerance, including the new ADA nutrition recommendations and standards of care, implications from the DCCT, and more. And its succinct, well-organized format makes it easy to find the information you need quickly. Softcover; 112 pages. #PMMT2
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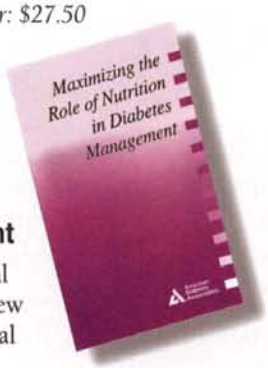

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Reference: 1. Korte JJ, Cooper Research, Inc, Cincinnati, Ohio. *The National Preference Trial: A study of patient preferences among blood glucose monitors.* August 1994. Data on file, Boehringer Mannheim Corporation.