Beginning in July 1994, all authors must submit with their manuscripts a duality of interest disclosure statement. This form can be found in every issue of ***Diabetes*** *and* ***Diabetes Care****, along with a copyright transfer agreement. The Association has long had a policy of requiring volunteers and senior staff to disclose any dualities of interest; this form simply clarifies the nature of what must be reported and provides a uniform means of doing so. Following is the entire text of the American Diabetes Association's policy statement explaining why the Association feels disclosure is important and how it is to be implemented.*

American Diabetes Association Policy Statement on Duality of Interest

Volunteers and senior staff of the American Diabetes Association contribute to the mission of the organization in various ways. They participate on the Board of Directors, committees, and task forces, and deal with issues that have far-reaching implications. The Association is well served by the fact that many of those involved have diverse interests and are involved in a number of activities outside the Association. This interest and involvement enhances the expertise these individuals bring to the various roles they fill in representing the Association.

On occassion, however, situations arise in which an individual serving the Association in an elected or appointed position, or as a senior staff member, has a duality of interest that may be, or could be perceived as, a relevant duality of interest or even a conflict of interest. Generally, a relevant duality of interest could be said to exist when individuals have material interests outside the Association that could influence them or could be perceived as influencing them to act contrary to the interests of the Association and for their own personal benefit or that of a family member or a business associate. Most often, a relevant duality of interest is financial, such as when an individual has an employment relationship, a stock ownership interest, or a consultative or advisory arrangement, or receives a grant or stipend. In some situations a conflict of interest may exist even though the conflict does not arise out of financial considerations.

In addition, health-care professionals frequently contribute to the scientific and medical programs and activities sponsored by the Association. Such contributions are often made with support from the biomedical industry. Guidelines from the Accreditation Council for Continuing Medical Education (the continuing medical education certification body that authorizes the provision of CME credits) specifies that all contributors must disclose to the sponsoring body their relationship with the biomedical industry. Thus it is now mandatory that participants in CME events disclose all relevant dualities of interest. In addition, a similar practice is now in effect between authors and the journals and publications to which they contribute papers.

PURPOSE OF THE POLICY

A key element in monitoring relevant dualities of interest and in avoiding potential conflicts of interest is a system in which those serving the Association provide disclosure of their interests. By disclosing such interests to the Association, the Association can determine if a duality of interest is relevant and can determine the steps that should be taken to minimize the likelihood that a conflict would arise.

It is not the intent of this policy to prohibit or discourage anyone from participation in the activities of the Association. Closely related dualities of interest are not inherently wrong or bad, but the Association must be made aware of such interests in order to be able to evaluate fully their impact on the mission and activities of the Association.

SCOPE OF THE POLICY

The following categories of volunteers and staff are required to disclose to the Association any dualities of interest that may be relevant to the work of the Association:

1. members of the Board of Directors;
2. senior staff;
3. all authors, editors, and editorial board members of ADA publications;
4. all speakers/presenters in continuing medical education events, including presenters of original scientific research;
5. other members of committees and task forces whose work focuses on continuing medical education or focuses on scientific/medical issues that are of interest to the biomedical industry.

Reviewers of manuscripts need not make a formal disclosure of their relevant dualities of interest. However, reviewers are encouraged to disqualify themselves from reviewing any manuscript that deals with a matter in which they or an immediate family member has a direct interest.

TYPES OF DUAL INTERESTS THAT SHOULD BE REPORTED

The following relationships must be disclosed to the Association:

1. Employment. The name and nature of all employers must be disclosed.
2. Membership on the board of directors or any fiduciary relationship with another organization.
3. Membership on a scientific advisory panel or other standing scientific/medical committees of another organization.

4. Stock ownership. Shares of stock directly owned or controlled, including those owned or controlled by an immediate family member.
5. All consultative or advisory arrangements for which monetary compensation is received.
6. Grants/research support. Grants or research support from a company/organization whose products or services are directly related to the subject matter in a manuscript or presentation.

If relevant dualities exist for immediate family members they, too, should be disclosed.

It is obvious that all categories, conditions, or circumstances that should be disclosed cannot be listed. A reasonable test to guide decisions about what to disclose is to ask whether any particular affiliation or interest could cause embarrassment to the ADA, or to the individual or institution involved, or lead to questions about an individual's motives, if such affiliation or interest were made known.

REPORTING PROCESS

Those individuals affected by this policy must complete a Duality of Interest Disclosure Statement at the time they are appointed or elected to a new term or become officially associated with an activity of the Association as defined above (see Scope of the Policy). Thereafter, a new Statement must be completed annually. Members of the staff required to complete the form will do so annually. Additionally, those completing a Statement are expected to notify the Association in writing if there are any material changes since the last form was completed. All completed statements will be kept strictly confidential.

ETHICS SUBCOMMITTEE OF THE AUDIT COMMITTEE

The purpose of this Subcommittee is to develop, approve, and evaluate the Disclosure Statement(s) used by the Association; to review the reporting and disclosure process to ensure that it is consistent with the purpose of this policy; to make regular reports to the Board of Directors to affirm that all members of the Board and senior staff have completed Disclosure Statements; to review, approve, and monitor the process and method by which there is disclosure of relevant dualities of interest in publications and programs; to provide recommendations or instructions to individuals completing a Disclosure Statement regarding actions that should or must be taken to reduce or eliminate a potential or real conflict; and to review this policy and make recommendations for revision whenever appropriate.

The subcommittee will consist of five members. The chair of the subcommittee will be appointed from the members of the Audit Committee. Two of the subcommittee members will be past officers of the Association, and two of the members will be individuals who have not participated in any activities of the Association. At least three of the members will have medical/scientific backgrounds. The members of the subcommittee will be appointed by the Committee on Councils and Committees for one staggered term of two years, and the chair will be selected from the elected members of the Audit Committee.

IF A RELEVANT DUALITY OF INTEREST ARISES

In any matter coming before the Board of Directors, committees, or a task force in which an individual has a relevant duality of interest or a real conflict occurs, the individual affected shall leave the room in which the meeting is being held and refrain from any discussions or actions on that subject. In most situations, no further action will be required. However, in some instances, the nature of the situation may require other actions be taken. The minutes of the meeting will reflect abstentions from voting due to these circumstances.

In the case of scientific/medical presentations or publications, those individuals with a relevant duality of interest will be identified in the program or publication.

DUALITY OF INTEREST DISCLOSURE FORM FOR AUTHORS OF ARTICLES IN AMERICAN DIABETES ASSOCIATION PUBLICATIONS

I have read the American Diabetes Association's Duality of Interest Policy Statement (found in the January and July issues of *Diabetes* and *Diabetes Care*), and I am indicating below that I have or have not had in the previous 12 months a relevant duality of interest with a company whose products or services are *directly* related to the subject matter of my manuscript. A relevant duality of interest includes employment, membership on the board of directors or any fiduciary relationship, membership on a scientific advisory panel or other standing scientific/medical committee, ownership of stock, receipt of honoraria or consulting fees, or receipt of financial support or grants for research. Company is defined as a for-profit concern engaged in the development, manufacture, or sale of pharmaceutical or biomedical devices or supplies.

Each author must sign this form. (The form may be photocopied if needed.)

	Check each area that applies					
	Yes	No	Yes	No	Yes	No
Employment	____	____	____	____	____	____
Membership on an advisory panel, standing committee, or board of directors	____	____	____	____	____	____
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Signature	_____		_____		_____	
Date	_____		_____		_____	

For each item checked "yes," please list on a separate sheet of paper the third-party organization with whom you have relevant affiliations or interests. Please provide sufficient information to enable the American Diabetes Association to make an informed decision. Include *1*) the nature of the activity that is a relevant duality, *2*) the type of financial arrangement, if any, between you and the third party, and *3*) a description of the business or purpose of the third party. Please see the following sample disclosures.

SAMPLE DISCLOSURES FOR AUTHORS

Employment
I am employed by Exacta Pharmaceutical Company (6250 Longwood Avenue, Any City, Missouri). My employer manufactures and markets pharmaceuticals related to the treatment of diabetes and its complications.

Board Membership
I am on the board of directors of the Exacta Pharmaceutical Company, a manufacturer of pharmaceuticals related to the treatment of diabetes.

Stock Shareholder
I, or my immediate family, hold stock in the following companies that make products related to the treatment or management of diabetes and its complications:

XYZ Corporation
LMN Corporation

Honoraria or Consulting Fees
I have received honoraria for speaking engagements from the following:

XYZ Corporation
LMN Corporation

I am a paid consultant of the XYZ Corporation.

Grants
The XYZ Corporation is providing funds to my laboratory in order to conduct studies on a new drug to treat diabetic neuropathy.

By answering "yes" in any category, the Association will disclose the relevant duality of interest. The Association will make the disclosure by placing an asterisk by the author's name, and in a footnote describe the nature of the duality of interest, e.g., stock ownership or grant support, and the third party involved.

This form must be returned with your submission. Make additional copies as needed for all authors. Failure to complete the disclosure may delay or prevent publication of your article.

COPYRIGHT TRANSFER AND STATEMENT OF ORIGINALITY

We approve the submission of this paper to the American Diabetes Association for publication and have taken due care to ensure the integrity of this work. We confirm that neither the manuscript nor any part of it has been published or is under consideration for publication elsewhere (abstracts excluded). Any reference to or use of previously published material protected by copyright is explicitly acknowledged in the manuscript.

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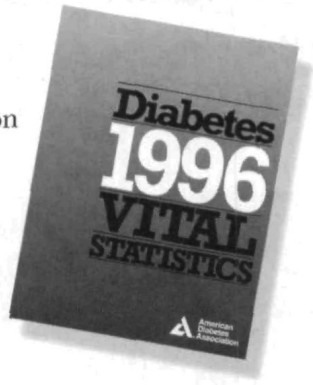
Diabetes: 1996 Vital Statistics



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American Diabetes Association.

CALL FOR APPLICATIONS

Editor-In-Chief

The American Diabetes Association invites applications for the position of editor-in-chief of *Diabetes Forecast*, the Association's monthly magazine for people with diabetes and their families.

The editor-in-chief has primary responsibility for presenting comprehensive, accurate, and timely information to people with diabetes on all aspects of treatment and self-care.

The appointment is for three years (effective Jan. 1, 1999 through Dec. 31, 2001). Interested parties should submit a letter of intent by February 1, 1998. A resume or curriculum vitae should be included. Further instructions will follow upon receipt of the letter of intent.

Please address correspondence to:

Larry Deeb, MD
Chair, Publications Policy Committee
American Diabetes Association
1660 Duke Street
Alexandria, VA 22314
Attention: Susan Lau

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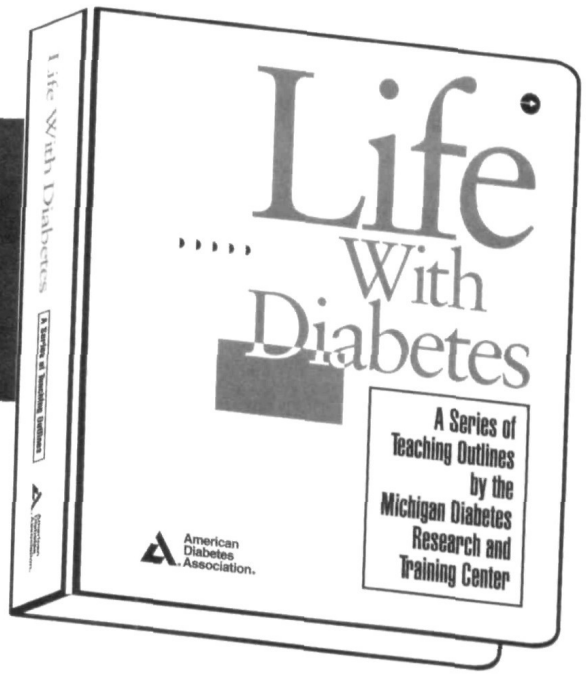

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Written to guide health professionals in the education of patients with diabetes, the outlines provide information on a diverse range of topics relevant to good diabetes self-management. Topics include: meal planning and nutrition, exercise, monitoring, sexual issues, and more. While primarily geared toward adults with either type 1 or type 2 diabetes, the content can easily be adapted to younger audiences.

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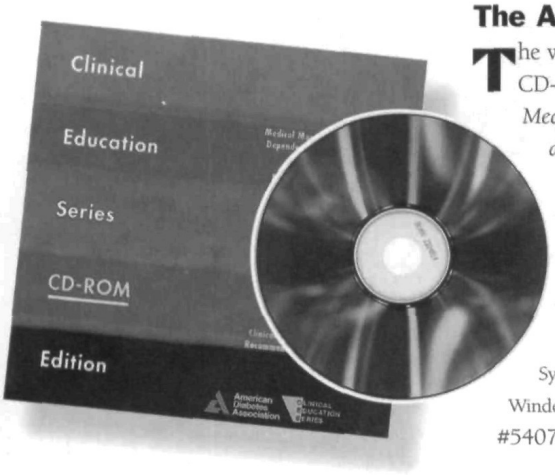

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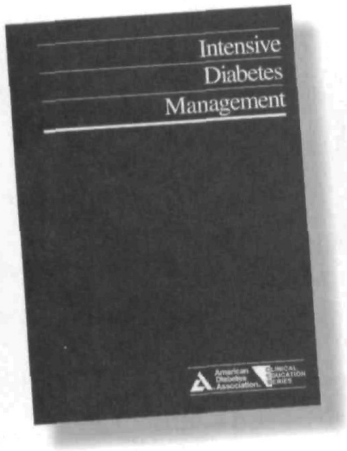

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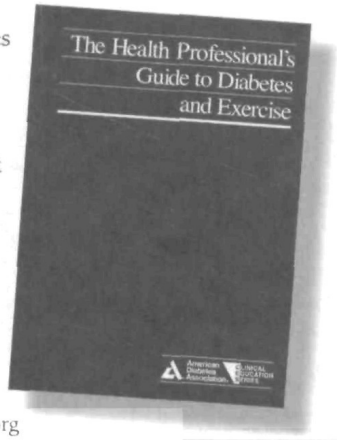

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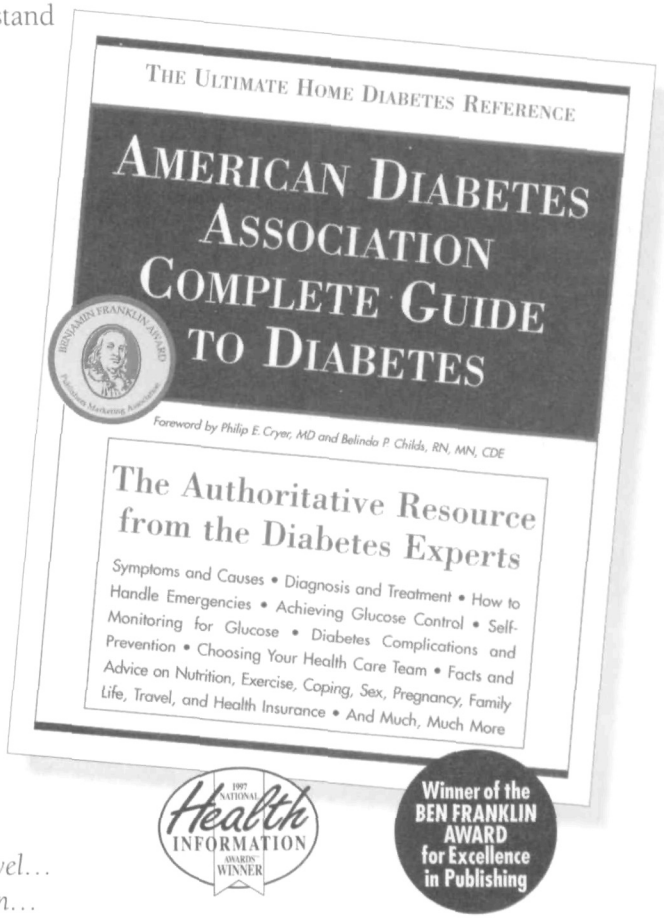

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GLUCOTROL XL® (glipizide) Extended Release Tablets *For Oral Use*

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 - arthralgia, 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.

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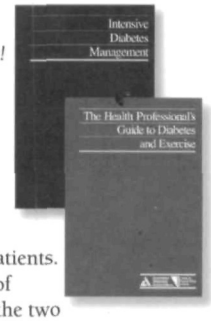

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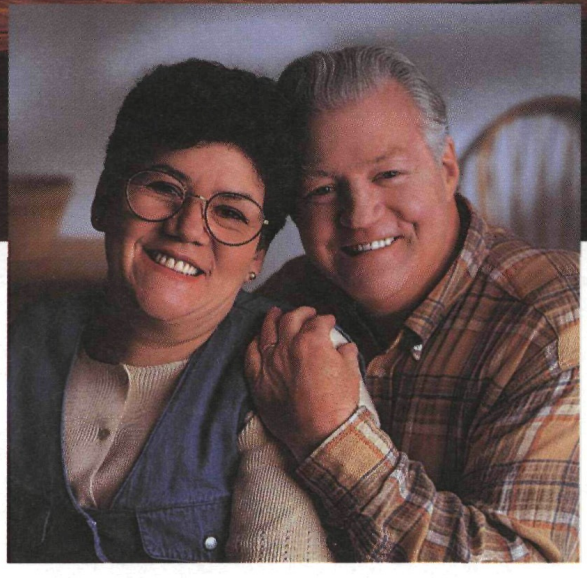

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†Gastrointestinal therapeutic system.

As with all sulfonylureas, hypoglycemia may occur.

Please see brief summary of prescribing information on adjacent page.

Reference: 1. Testa MA, Simonson DC. Beneficial effects of glipizide GITS on glycemic control, quality of life and symptom distress in NIDDM. *Diabetes.* May 1996;45(suppl 2):123A. Abstract 450.