

PRONUNCIATION: (tole-AZ-ah-mide)

COMMON BRAND NAME(S): Tolinase

HOW TO USE: Take this medication by mouth, usually once daily with breakfast or the first main meal, or as directed by your doctor. Some patients, especially those taking higher doses, may be directed to take this drug twice a day with the morning and evening meals. The dosage is based on your medical condition and response to therapy. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day.

USES: Tolazamide is used along with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes (non-insulin-dependent diabetes). Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems. Proper control of diabetes may also lessen your risk of a heart attack or stroke. Tolazamide belongs to the class of drugs known as sulfonylureas. It works by stimulating the release of your body's natural insulin, thereby lowering your blood sugar.

SIDE EFFECTS: Stomach cramps, bloating, heartburn, loss of appetite, constipation, diarrhea, nausea, vomiting, or weight gain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: sun sensitivity, skin changes (e.g., darkening, thickening), unusual fatigue, fast/pounding heartbeat, easy bruising/bleeding, mental/mood changes, sudden weight gain, swelling of the hands/feet, muscle weakness/spasm. Tell your doctor immediately if any of these rare but very serious side effects occur: yellowing eyes or skin, persistent nausea/vomiting, severe stomach/abdominal pain, dark urine, signs of infection (e.g., fever, persistent sore throat), seizures. This medication can cause low blood sugar (hypoglycemia). This effect may occur if you do not consume enough calories (from food, juices, fruit, etc.). The symptoms include chills, cold sweat, blurred vision, dizziness, drowsiness, shaking, rapid heart rate, weakness, headache, fainting, tingling of the hands or feet, or hunger. It is a good habit to carry glucose tablets or gel to treat low blood sugar. If you are in a situation where you don't have these reliable forms of glucose, eat a quick source of sugar such as table sugar, honey, or candy, or drink a glass of orange juice or non-diet soda to quickly raise your blood sugar level. Tell your doctor immediately about the reaction. To help prevent hypoglycemia, eat meals on a regular schedule and do not skip meals. Closely monitor your blood sugar levels for at least 1-2 days after an episode of hypoglycemia. Check with your doctor or pharmacist about what you should do if you miss a meal. Symptoms of high blood sugar (hyperglycemia) include thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, or fruity breath odor. If these symptoms occur, tell your doctor immediately. Your medication dosage may need to be increased. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS: Before taking tolazamide, tell your doctor or pharmacist if you are allergic to it; or to other sulfonylurea drugs (e.g., glyburide, tolbutamide); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. This medication should not be used if you have certain medical

conditions. Before using this medicine, consult your doctor or pharmacist if you have: a certain metabolic condition (diabetic ketoacidosis), severe kidney disease. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, thyroid problems, poor diet, irregular eating patterns, certain hormonal conditions (adrenal/pituitary insufficiency, SIADH-syndrome of inappropriate secretion of antidiuretic hormone), mineral imbalance (low sodium blood level). You may experience blurred vision, dizziness, or drowsiness due to extremely low or high blood sugar levels. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcohol while taking this medication because it can increase the risk of developing low blood sugar. Rarely, alcohol can interact with tolazamide and cause a serious reaction (disulfiram-like reaction) with symptoms such as facial flushing, nausea, vomiting, dizziness, or stomach pain. Consult your doctor or pharmacist about the safe use of alcohol. During times of stress, such as fever, infection, injury, or surgery, it may be more difficult to control your blood sugar. Consult your doctor as a change in your medication or how often you test your blood sugar may be required. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths and sunlamps. Use a sunscreen and wear protective clothing when outdoors. Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially low blood sugar. This medication should be used only when clearly needed during pregnancy. It is not recommended for use for at least 2 weeks before delivery because it may cause low blood sugar in the newborn. Your doctor may substitute insulin for this drug during your pregnancy. Follow all instructions carefully. Discuss the risks and benefits with your doctor. It is unknown if this drug passes into breast milk. However, similar drugs pass into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop, or change the dosage of any medicine before checking with them first. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: "blood thinners" (e.g., warfarin), bupropion, certain herbal drugs (fenugreek, ginseng, gymnema), MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranlycypromine), sulfa drugs (e.g., sulfamethoxazole), drugs that may decrease your blood sugar levels (e.g., high-dose salicylates), drugs that may increase your blood sugar levels (including corticosteroids such as hydrocortisone or prednisone, diet pills, niacin, "water pills"/diuretics such as furosemide or hydrochlorothiazide, protease inhibitors such as ritonavir or saquinavir, certain anti-psychotic drugs such as clozapine or olanzapine). Beta-blocker medications (e.g., metoprolol, propranolol, glaucoma eye drops such as timolol) may prevent the fast/pounding heartbeat you would usually feel when your blood sugar level falls too low (hypoglycemia). Other symptoms of low blood sugar such as dizziness, hunger, or sweating are unaffected by these drugs. Check all prescription and nonprescription medicine labels carefully since many contain pain relievers/fever reducers (non-steroidal anti-inflammatory drugs-NSAIDs such as ibuprofen, naproxen, or aspirin) that may increase your risk of hypoglycemia. Low-dose aspirin, as prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually these dosages are 81-325 milligrams per day), should be continued. Consult your doctor or pharmacist about the safe use of these drugs. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include:

shakiness, rapid heartbeat, unexplained sweating, loss of consciousness, seizures.

NOTES: Do not share this medication with others. It is recommended that you attend a diabetes education program to understand diabetes and all the important aspects of its treatment including meals/diet, exercise, personal hygiene, medications, and getting regular eye, foot and medical exams. Keep all medical appointments. Laboratory and/or medical tests (e.g., liver and kidney function tests, fasting blood glucose, hemoglobin A1c, complete blood counts) should be performed periodically to monitor for side effects and response to therapy. Regularly check your blood sugar levels if so directed by your doctor or pharmacist.

MISSED DOSE: If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE: Store at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

WARNING: No Information Available. Please Consult Your Health Care Provider or Pharmacist.