

PRONUNCIATION: (toll-BYOU-tuh-mide)

HOW TO USE: Take this medication by mouth as directed by your doctor. The dosage is based on your medical condition and response to treatment. Your doctor may direct you to take a low dose at first, gradually increasing the dose to lower the chance of side effects such as upset stomach and low blood sugar. Your doctor will adjust your dose based on your blood sugar levels to find the best dose for you. Follow your doctor's directions carefully. The usual maximum dose for adults is 2000 milligrams each day. If you are already taking another anti-diabetic drug (e.g., metformin, insulin), follow your doctor's directions carefully for stopping/continuing the old drug and starting tolbutamide. Use this medication regularly to get the most benefit from it. To help you remember, take it at the same times each day.

USES: Tolbutamide is used 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. Tolbutamide belongs to the class of drugs known as sulfonylureas. It works by causing the release of your body's natural insulin and may help to restore your body's proper response to insulin.

SIDE EFFECTS: Stomach upset/fullness, nausea, headache, or weight gain may occur. If any of these effects persist or worsen, tell 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 rare but very serious side effects occur: dark urine, easy bleeding/bruising, persistent nausea, severe stomach/abdominal pain, signs of infection (e.g., persistent sore throat, fever), yellowing eyes/skin. This medication may cause low blood sugar (hypoglycemia), especially if you take other medications for diabetes, drink large amounts of alcohol, do unusually heavy exercise, or do not consume enough calories from food. Symptoms include cold sweat, blurred vision, dizziness, drowsiness, shaking, fast heartbeat, headache, fainting, tingling of the hands/feet, and hunger. It is a good habit to carry glucose tablets or gel to treat low blood sugar. If you don't have these reliable forms of glucose, rapidly raise your blood sugar by eating a quick source of sugar such as table sugar, honey, or candy, or drink fruit juice or non-diet soda. Promptly tell your doctor about the reaction. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. Check with your doctor or pharmacist to find out what you should do if you miss a meal. Symptoms of high blood sugar (hyperglycemia) include thirst, increased urination, confusion, drowsiness, flushing, rapid breathing, and fruity breath odor. If these symptoms occur, tell your doctor promptly. Your dosage may need to be increased. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: 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 tolbutamide, tell your doctor or pharmacist if you are allergic to it; 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: metabolic acidosis (e.g., diabetic ketoacidosis), serious infection. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney

disease, liver disease, low sodium blood level (hyponatremia), certain hormonal conditions (adrenal/pituitary insufficiency, thyroid disease, syndrome of inappropriate antidiuretic hormone-SIADH), use/abuse of alcohol. 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 your risk of developing low blood sugar. Rarely, alcohol can interact with tolbutamide and cause a serious reaction with symptoms such as facial flushing, nausea, vomiting, dizziness, or stomach pain. If you notice any of these effects, tell your doctor immediately. It may be harder to control your blood sugar when your body is stressed (e.g., due to fever, infection, injury, or surgery). Consult your doctor because this may require a change in your treatment plan, medications, or blood sugar testing. 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 the effects of the drug, especially low blood sugar. During pregnancy, this medication should be used only when clearly needed. Your doctor may direct you to switch to insulin treatment during pregnancy. If you are using tolbutamide during your pregnancy, your doctor may switch you to insulin before the expected delivery date because of the risk of low blood sugar in your newborn. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Though there have been no reports of harm to nursing infants, consult your doctor before breast-feeding.

DRUG INTERACTIONS: Your doctor or pharmacist may already be aware of any possible drug interactions and may be monitoring you for them. 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: azole antifungals, (e.g., fluconazole, ketoconazole), "water pills"/diuretics (e.g., furosemide, hydrochlorothiazide). Many drugs can affect your blood sugar levels, making it more difficult to control your blood sugar. Before you start, stop, or change any medication, talk with your doctor or pharmacist about how the medication may affect your blood sugar. Check your blood sugar levels regularly as directed by your doctor. Tell your doctor about the results and of any symptoms of high or low blood sugar. (See also Side Effects section.) Your doctor may need to adjust your anti-diabetic medication, exercise program, or diet. Beta blocker medications (e.g., metoprolol, propranolol) 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 the labels on nonprescription/herbal products carefully. Some products contain sugar/alcohol and may affect your blood sugar levels. Ask your doctor or pharmacist about using these products safely. 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. Canada residents can call a provincial poison control center. Symptoms of overdose may include: shakiness, fast heartbeat, sweating, loss of consciousness.

NOTES: Do not share this medication with others. You should attend a diabetes education program to learn more about diabetes and all the important aspects of its treatment, including meals/diet, exercise, personal hygiene, medications, and getting regular eye/foot/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 check

for side effects and monitor your response to treatment. Check your blood sugar levels regularly as directed.

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 59-86 degrees F (15-30 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.