

PRONUNCIATION: (GLEYE-byou-ride/met-FOR-min)

COMMON BRAND NAME(S): Glucovance

HOW TO USE: Read the Patient Information Leaflet available from your pharmacist before you start using this medication and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Take this medication by mouth, usually once or twice a day with meals or as directed by your doctor. Drink plenty of fluids while taking this medication unless otherwise directed by your doctor. The dosage is based on your medical condition and response to therapy. 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 of metformin and 20 milligrams of glyburide each day. If you are already taking another anti-diabetic drug (e.g., chlorpropamide), follow your doctor's directions carefully for stopping the old drug and starting this combination medication. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day. Inform your doctor if your condition persists or worsens (e.g., high/low blood sugar levels). It may take up to 2 weeks before the full benefit of this drug takes effect.

USES: This anti-diabetic medication is a combination of 2 drugs (glyburide and metformin). It is used along with a diet and exercise program to control high blood sugar in patients with type 2 diabetes (non-insulin-dependent diabetes). Glyburide is a sulfonylurea and works by stimulating the release of your body's natural insulin and by decreasing the amount of sugar that your liver makes. Metformin is a biguanide and works by decreasing the amount of sugar that your liver makes and that your stomach/intestines absorb. Both of these medications work by helping to restore your body's proper response to the insulin you naturally produce. 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.

SIDE EFFECTS: See also Warning section. Nausea, stomach upset, diarrhea, or weight gain may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. If stomach symptoms return later (after you are on the same dose for several days or weeks), tell your doctor immediately. Stomach symptoms that occur after the first days of your treatment may be a sign of lactic acidosis. 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: easy bleeding/bruising, signs of infection (e.g., persistent sore throat, fever), persistent nausea, severe stomach/abdominal pain, yellowing eyes/skin, dark urine. 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. Tell your doctor about the reaction immediately. 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 immediately. 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 symptoms of a serious allergic reaction,

including: 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 this medication, tell your doctor or pharmacist if you are allergic to glyburide or metformin; 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: kidney disease, liver disease, conditions that may cause a low level of oxygen in the blood or poor circulation (e.g., severe congestive heart failure, recent heart attack, recent stroke), metabolic acidosis (e.g., diabetic ketoacidosis), serious infection, severe loss of body fluids (dehydration). Before using this medication, tell your doctor or pharmacist your medical history, especially of: alcohol use, severe breathing problems (e.g., obstructive lung disease, severe asthma), blood problems (e.g., anemia, vitamin B12 deficiency), electrolyte imbalance (hyponatremia), fertility problems (e.g., ovulation problems), certain hormonal conditions (adrenal/pituitary insufficiency, thyroid disease, syndrome of inappropriate antidiuretic hormone-SIADH), certain nervous system problem (autonomic neuropathy). Before having surgery or any X-ray/scanning procedure using injectable iodinated contrast material, tell your doctor that you are taking this medication. You will need to temporarily stop this medication before the time of your surgery/procedure. Consult your doctor for further instructions. 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 and lactic acidosis. Rarely, alcohol can interact with glyburide 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 using alcohol safely. 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. Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be at greater risk for side effects such as lactic acidosis or low blood sugar while using this drug. This medication can cause changes in the menstrual cycle (promote ovulation) and increase the risk of becoming pregnant. Consult your doctor or pharmacist about the use of reliable birth control while using this medication. During pregnancy, this medication should be used only when clearly needed. Insulin treatment may be preferred during pregnancy. If you are using glyburide during your pregnancy, your doctor may switch you to insulin at least 2 weeks before the expected delivery date because of glyburide's risk of low blood sugar in your newborn. Discuss the risks and benefits with your doctor. Follow your doctor's instructions carefully. This drug passes into breast milk in small amounts. 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. This drug should not be used with the following medication because a very serious interaction may occur: bosentan. If you are currently using the medication listed above, tell your doctor or pharmacist before starting this medication. 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), colestevlam, drugs that may affect the kidneys' ability to remove metformin from the body (e.g., cimetidine, cephalexin),

"water pills"/diuretics (e.g., furosemide, thiazide diuretics such as 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. Some medications (e.g., beta blockers such as propranolol) may mask 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 may contain sugar/alcohol and may affect blood sugars. Ask your doctor or pharmacist about using these products safely. Cimetidine is a nonprescription drug that is commonly used to treat extra stomach acid. Because it may interact with metformin, ask your pharmacist about other products to treat stomach acid. 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. Overdose can cause lactic acidosis and low blood sugar. Symptoms of overdose may include: rapid breathing, severe drowsiness, slow/irregular heartbeat.

**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 therapy. 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 at 77 degrees F (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:** Metformin can rarely cause a serious (sometimes fatal) condition called lactic acidosis. Stop taking this medication and seek immediate medical attention if you develop any of the following symptoms of lactic acidosis: unusual tiredness, severe drowsiness, chills, blue/cold skin, muscle pain, fast/difficult breathing, unusually slow/irregular heartbeat. Lactic acidosis is more likely to occur in patients who have certain medical conditions, including kidney or liver disease, conditions that may cause a low oxygen blood level or poor circulation (e.g., severe congestive heart failure, recent heart attack, recent stroke), heavy alcohol use, a severe loss of body fluids (dehydration), X-ray or scanning procedures that require an injectable iodinated contrast drug, recent surgery, or a serious infection. Tell your doctor immediately if any of these conditions occur or if you notice a big change in your overall health. You may need to stop taking metformin temporarily. The elderly are also at

higher risk, especially those older than 80 years who have not had kidney tests. (See also Side Effects and Precautions sections.)

**MEDICAL ALERT:** Your condition can cause complications in a medical emergency. For information about enrolling in MedicAlert, call 1-800-854-1166 (USA) or 1-800-668-1507 (Canada).