

PRONUNCIATION: (PYE-oh-GLI-ta-zone/glih-MEH-pih-ride)

COMMON BRAND NAME(S): Duetact

HOW TO USE: Read the Medication Guide provided by your pharmacist before you start taking this medication and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth, usually once daily with the first main meal of the day or as directed by your doctor. The dosage is based on your medical condition and response to treatment. Do not take more than 45 milligrams of pioglitazone a day. Use this medication regularly in order to get the most benefit from it. Remember to take it at the same time each day. Monitor your blood sugar levels on a regular basis, and share the results with your doctor. It may take up to 2 to 3 months before you get the full benefit of this drug. When switching from individual diabetes drugs to this combination product, your doctor may ask you to check your blood sugar more often to make sure you do not have a sudden attack of low blood sugar (hypoglycemic reaction) when starting this product. (See also Side Effects section.) Follow your doctor's directions carefully.

USES: This medication is a combination of 2 drugs, pioglitazone and glimepiride. It is used along with a proper diet and exercise program to control high blood sugar in patients 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. Pioglitazone belongs to a class of drugs known as thiazolidinediones or "glitazones." It works by helping to restore your body's proper response to insulin, thereby lowering your blood sugar. Glimepiride belongs to a class of drugs known as sulfonylureas. It works by causing the release of your body's natural insulin.

SIDE EFFECTS: See also Warning section. Headache, dizziness, diarrhea, nausea, muscle pain, sore throat, or tooth problems 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 unlikely but serious side effects occur: new/worsening vision problems (e.g., color or night vision problems), bone fracture. Tell your doctor immediately if any of these rare but very serious side effects occur: loss of appetite, yellowing eyes/skin, dark urine, mental/mood changes (e.g., hallucinations, confusion), seizures, easy bruising/bleeding, signs of infection (e.g., fever, persistent sore throat). This medication can cause low blood sugar (hypoglycemia). This may occur if you do not consume enough calories from food or if you do unusually heavy exercise. 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 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 this medication, tell your doctor or pharmacist if you are allergic to pioglitazone or glimepiride; or to other "glitazones" (e.g., rosiglitazone); or to other sulfonylureas (e.g., glipizide, 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: type 1 diabetes (insulin-dependent diabetes), very high blood sugar levels (diabetic ketoacidosis), newly diagnosed or worsening heart failure (acute congestive heart failure), history of liver disease, active liver disease. Before taking this medication, tell your doctor or pharmacist your medical history, especially of: heart problems (e.g., chronic congestive heart failure), fluid in your lungs, swelling (edema, fluid retention), liver problems, kidney disease, thyroid problems, certain hormonal conditions (adrenal/pituitary insufficiency, syndrome of inappropriate secretion of antidiuretic hormone-SIADH), mineral imbalance (hyponatremia), anemia, eye (retina) problems. 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 (hypoglycemia). It may be harder to control your blood sugar when your body is stressed (e.g., due to fever, infection, injury, or surgery). In these cases, consult your doctor because you 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. This medication may increase the risk of bone fracture (e.g., upper arm, hand, foot, ankle) in female patients. To lower the chance of getting injured, use caution when doing activities such as contact sports. Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, the elderly may be at greater risk for low blood sugar while using this drug. This medication can cause changes in the menstrual cycle (promote ovulation) in women with certain fertility problems. Women of child-bearing age should use a reliable form of birth control while taking this medication. Consult your doctor for more details. This medication is not recommended for use during pregnancy. Your doctor may direct you to switch to insulin treatment during your pregnancy. Use of pioglitazone/glimepiride close to the expected delivery date may increase the risk of low blood sugar in your newborn. Consult your doctor for more details, and follow all instructions carefully. It is unknown if this medication passes into breast milk, and it may have undesirable effects on a nursing infant. Breast-feeding while using this drug is not recommended. 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: high doses of aspirin or aspirin-like drugs (e.g., salicylates, nonsteroidal anti-inflammatory drugs-NSAIDs such as ibuprofen, phenylbutazone), atypical antipsychotics (e.g., aripiprazole, clozapine, olanzapine, risperidone, ziprasidone), azole antifungals (e.g., fluconazole, ketoconazole, miconazole), hormonal birth control pills, bupropion, chloramphenicol, clofibrate, decongestants (e.g., pseudoephedrine), diazoxide, diet pills, epinephrine, estrogens, herbal/supplement products (e.g., fenugreek, ginseng, gymnema), insulin, isoniazid, MAO inhibitors (e.g., furazolidone, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, isocarboxazid, tranylcypromine), niacin, phenytoin, probenecid, sulfonamides (e.g., sulfa antibiotics), thyroid drugs, warfarin, "water pills" (diuretics such as hydrochlorothiazide, furosemide), drugs affecting liver enzymes that remove this medication from your body (e.g., gemfibrozil, rifamycins including rifampin). Many drugs can affect your blood sugar levels, making it more difficult to control your blood sugar. Examples include corticosteroids (such as

prednisone), psychiatric medicines (such as olanzapine), fluoroquinolone antibiotics (such as ciprofloxacin), among others. Ask your doctor or pharmacist how often to check your blood sugar. 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 diabetes medication, exercise program, or diet. 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 because many contain pain relievers/fever reducers (NSAIDs such as aspirin, ibuprofen, naproxen) that can affect your blood sugar levels. Low-dose aspirin should be continued if prescribed by your doctor for specific medical reasons such as heart attack or stroke prevention (usually at dosages of 81-325 milligrams per day). Consult your doctor or pharmacist for more details. 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 should call the US National Poison Hotline at 1-800-222-1222. Canada residents should 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. Lifestyle changes that help promote healthy bones include increasing weight-bearing exercise, eating well-balanced meals containing adequate calcium and vitamin D, stopping smoking, and limiting alcohol. Consult your doctor to see if you need to take calcium/vitamin D supplements and discuss lifestyle changes that might benefit you. 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 at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. 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:** This medication may infrequently cause or worsen a certain heart problem (congestive heart failure). Tell your doctor immediately if you notice any symptoms of heart failure, including: swelling of the hands/feet, unusual/sudden weight gain, trouble breathing, or unusual tiredness.