

**PRONUNCIATION:** (reh-PAGG-lin-ide/met-FOR-min)

**COMMON BRAND NAME(S):** Prandimet

**HOW TO USE:** Take this medication by mouth 15 minutes before a meal, usually 2-3 times a day or as directed by your doctor. Take this drug no earlier than 30 minutes before the meal. You may also take it just before the meal if necessary. Do not take a dose of medication if you are skipping a meal. 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 treatment. Your doctor will adjust your dose based on your blood sugar levels to find the best dose for you. Your doctor may start you on a lower dose of metformin and gradually increase the dose to lower the chance of side effects such as upset stomach. Follow your doctor's directions carefully. If you are changing from a different anti-diabetic drug (such as 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. Carefully follow the medication treatment plan, meal plan, and exercise program your doctor has recommended. Check your blood sugar regularly as directed by your doctor. Keep track of the results and share them with your doctor. Tell your doctor if your blood sugar measurements are too high or too low. Your treatment plan may need to be changed.

**USES:** This anti-diabetic medication is a combination of 2 drugs (repaglinide 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). Repaglinide works by stimulating the release of your body's natural insulin. 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. This medication should not be used to treat people with type 1 diabetes (insulin-dependent diabetes).

**SIDE EFFECTS:** See also Warning section. Nausea, diarrhea, and upset stomach may occur as your body adjusts to the metformin. Weight gain and joint pain may also 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. This medication may cause low blood sugar (hypoglycemia), especially if you 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:** See also Warning section. Before taking this medication, tell your doctor or pharmacist if you are allergic to repaglinide 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. Before using this medication, tell your doctor or pharmacist your medical history, especially of: severe breathing problems (such as obstructive lung disease, severe asthma), blood problems (such as anemia, vitamin B12 deficiency), heart problems (such as heart failure, recent heart attack), liver disease, recent stroke. 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 hypoglycemia and lactic acidosis. Consult your doctor or pharmacist about using alcohol safely. It may be harder to control your blood sugar when your body is stressed (such as fever, infection, injury, or surgery). Tell your doctor if you get a serious infection or injury. Your doctor may need to adjust your diabetes medication, exercise program, or diet. This medication can cause changes in the menstrual cycle and make it easier to become pregnant. If you do not want to become pregnant, consult your doctor or pharmacist about using reliable birth control. During pregnancy, this medication should be used only when clearly needed. Insulin treatment may be preferred during pregnancy. Discuss the risks and benefits with your doctor. Follow your doctor's instructions carefully. This medication passes into breast milk and may have undesirable effects on a nursing infant. Breast-feeding while using this medication is not recommended. Consult your doctor before breast-feeding.

**DRUG INTERACTIONS:** The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring. To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval. Some products that may interact with this drug include: NPH insulin, "water pills"/diuretics (such as furosemide, thiazide diuretics including hydrochlorothiazide). Other medications can affect the removal of repaglinide from your body, which may affect how repaglinide works. Examples include cyclosporine, gemfibrozil, trimethoprim, azole antifungals (such as itraconazole, ketoconazole), macrolide antibiotics (such as clarithromycin, erythromycin), rifamycins (such as rifabutin), St. John's wort, among others. Other drugs can affect the kidneys. This effect may slow down the removal of metformin from the body. Metformin may also slow down the removal of other drugs. Examples of affected drugs include some antibiotics (such as cephalexin, penicillin) and probenecid. 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 (such as 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 the labels on all your medicines (such as cough-and-cold products) carefully. Some products may contain sugar or alcohol and may affect your blood sugar levels. 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. Other medications can affect the results of urine tests for sugar or ketones. Consult your doctor or pharmacist for more information. This document does not contain all possible drug interactions. Keep a list of all the products you use. Share this list with your doctor and pharmacist to lessen your risk for serious medication problems.

**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: very fast heartbeat, vision changes, unexplained heavy sweating, agitation, fainting, seizures.

**NOTES:** Do not share this medication with others. Attend a diabetes education program to learn more about diabetes and the important aspects of its treatment, including medications, diet, exercise, and getting regular eye/foot/medical exams. Learn the symptoms of high and low blood sugar and how to treat low blood sugar. Check your blood sugar levels regularly as directed. Keep all medical appointments. Laboratory and/or medical tests (such as kidney function tests, fasting blood glucose, hemoglobin A1c, complete blood count) should be performed periodically to check for side effects and monitor your response to treatment.

**MISSED DOSE:** If you miss a dose, skip that dose and resume your regular dosage schedule with your next meal. Do not double the dose to catch up.

**STORAGE:** Store at room temperature between 59-77 degrees F (15-25 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, heavy alcohol use, loss of too much body water (dehydration), recent surgery, conditions that may cause a low oxygen blood level or poor circulation (such as severe congestive heart failure, recent heart attack, recent stroke), 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 temporarily stop this medication. Also tell your doctor that you are taking this medication before having surgery or any X-ray/scanning procedures that require an injectable iodinated contrast drug. Consult your doctor for further instructions. Older adults, especially those older than 80 years who have not had kidney tests, may be at greater risk for side effects such as lactic acidosis while using this drug. (See also Side Effects and Precautions sections.)