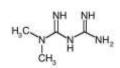
# (100 % EXPORT QUALITY MEDICINE









## **GENERIC NAME:** metformin

#### **DRUG CLASS AND MECHANISM**

Metformin is an oral medication that lowers blood glucose (sugar) and is used for treating type 2 diabetes. Insulin is a hormone produced by the pancreas that controls glucose levels in blood by reducing the amount of glucose made by the liver and by increasing the removal of glucose from the blood by muscle and fat tissues. As a result, blood glucose levels fall. Diabetes caused by a decrease in production of insulin that causes increased production of glucose by the liver, and reduced uptake (and effects) of insulin on fat and muscle tissues. Metformin acts by increasing the sensitivity of liver, muscle, fat, and other tissues to the uptake and effects of insulin. These actions lower the level of sugar in the blood.

Unlike glucose-lowering drugs of the sulfonylurea class, for example glyburide (Micronase; DiaBeta) or glipizide (Glucotrol), metformin does not increase the concentration of insulin in the blood and, therefore, does not cause excessively low blood glucose levels (hypoglycemia) when used alone. In scientific studies, metformin reduced the complications of diabetes such as heart disease, blindness and kidney disease. Metformin was approved by the FDA in December 1994.

## PRESCRIPTION: Yes

#### **GENERIC AVAILABLE: Yes**

PREPARATIONS: Tablets: 500, 850, and 1000 mg. Tablets (extended release): 500, 750, and 1000 mg. Solution: 500 mg/5 ml

#### PRESCRIBED FOR

**Metformin** is used for treating type 2 diabetes in adults and children. It may be used alone or in combination with other diabetic medications. Metformin also has been used to prevent the development of diabetes in people at risk for diabetes, treatment of polycystic ovaries, and weight gain due to medications used for treating psychoses.

## **DOSING**

For treating type 2 diabetes in adults, metformin (immediate release) usually is begun at a dose of 500 mg twice a day or 850 mg once daily. The dose is gradually increased by 500 mg weekly or 850 mg every two weeks as tolerated and based on the response of the levels of glucose in the blood. The maximum daily dose is 2550 mg given in three divided doses. If extended tablets are used, the starting dose is 500 mg or 1000 mg daily with the evening meal. The dose can be increased by 500 mg weekly up to a maximum dose of 2000 mg (2500 mg of Fortamet) once daily or in two divided doses. Glumetza tablets are given once daily. Metformin should be taken with meals.

For pediatric patients 10-16 years of age, the starting dose is 500 mg twice a day. The dose can be increased by 500 mg weekly up to a maximum dose of 2000 mg. Glucophage XR has not been studied in children.

## **DRUG INTERACTIONS**

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: birth control pills, high blood pressure drugs (beta-blockers such as propranolol, calcium channel blockers such as nifedipine, ACE inhibitors such as captopril), cimetidine, clomiphene, corticosteroids (e.g., prednisone), decongestants, other diabetes drugs (e.g., glyburide, insulin), estrogens, fenugreek, ginseng, isoniazid, niacin, phenothiazines (e.g., chlorpromazine), phenytoin, thyroid drugs, "water pills" (diuretics such as hydrochlorothiazide, furosemide). If you are scheduled to undergo any x-ray or scanning procedure using injectable iodinated contrast material, be sure to inform your doctor that you are taking this medication. You will need to temporarily stop this medication around the time of your procedure. Consult your doctor for further instructions.

## **USES**

This medication is a biguanide-type medicine that is used along with a diet and exercise program to control high blood sugar in diabetic patients. This medication works by helping to restore your body's proper response to the insulin you naturally produce, and by decreasing the amount of sugar that your liver makes and that your stomach/intestines absorb. Controlling high blood sugar helps prevent heart disease, strokes, kidney disease, blindness and circulation problems, as well as decreased sexual ability (impotence).

## **HOW TO USE**

This medication is best taken by mouth with meals. Drink plenty of fluids while taking this 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. Your dosage is based on your medical condition and response to therapy. This medication may come with a Patient Information Leaflet. Read it carefully and ask your doctor or pharmacist any questions you may have about your medication.

#### SIDE EFFECTS

Also see Warning section. Nausea, stomach upset, diarrhea or metallic taste may occur initially as your body adjusts to the medication. If stomach symptoms recur later (after you are on the same dose for several days or weeks), tell your doctor immediately. A late recurrence of stomach symptoms may be due to lactic acidosis. Remember that your doctor has prescribed this medication because 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 usually does not cause low blood sugar (hypoglycemia), but this effect may occur if you do not consume enough calories (from food, juices, fruit, etc.). The symptoms include chills, cold sweat, dizziness, drowsiness, shaking, rapid heartbeat, 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. 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, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

## **PRECAUTIONS**

Before taking metformin, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. 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 oxygen blood level or poor circulation (e.g., severe congestive heart failure, recent heart attack, recent stroke), metabolic acidosis (e.g., diabetic ketoacidosis), serious infection, lack of body fluids (dehydration). Before using this medication, tell your doctor or pharmacist your medical history, especially of: severe breathing problems (e.g., obstructive lung disease, severe asthma), blood problems (e.g., anemia, vitamin B-12 deficiency), scheduled upcoming surgery, scheduled upcoming x-ray or scanning procedures, fertility problems (e.g., ovulation problems), alcohol use. Limit alcohol while using this medication. 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 may be required. This medication can cause changes in the menstrual cycle (promote ovulation) in women with certain fertility problems, increasing the risk of becoming pregnant. Consult your doctor or pharmacist about the use of reliable birth control while using this medication. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Breast-feeding is not recommended while using this drug.

## **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: rapid or trouble breathing, severedrowsiness, slow or irregular heartbeat.

## MISSED DOSE

If you miss a dose, use 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 the U.S. product between 68-77 degrees F (20-25 degrees C) away from light and moisture. Brief storage from 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. . Store the Canadian product 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.

WARNING:-Metformin can rarely cause a condition called lactic acidosis, which can be fatal. Seek immediate medical attention if you develop any of the following symptoms of lactic acidosis: unusual tiredness (fatigue) or severe drowsiness, cold skin, muscle pain, breathing trouble or rapid breathing, unusually slow or irregular heartbeat. Lactic acidosis is more likely to occur in patients who have: 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), excessive alcohol use, a lack of body fluids (dehydration), X-ray or scanning procedures that require an injectable iodinated contrast drug, surgery, or a serious infection. Also at higher risk are those who are elderly, especially if you are over 80 years of age and have not had kidney and liver tests.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.





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