



Metformin tablets film-coated



COMPOSITION :

Metformin 500

Each uncoated Extended release tablet contains:

Metformin Hydrochloride equivalent Ip.....500mg

Metformin 850

Each uncoated Extended-release tablet contains:

Metformin Hydrochloride equivalent IP.....850mg

Metformin 1000

Each uncoated Extended-release tablet contains:

Metformin Hydrochloride equivalent IP.....1000mg

INDICATIONS :

Metformin tablets, used as a once per day, are indicated as an adjunct to diet and exercise, to lower blood glucose. Metformin can be used concomitantly with a sulphonylurea or insulin to improve glycaemic control in adults.

Metformin is indicated in patients 17 years of age and older as either monotherapy or in combination therapy.

DOSAGE AND ADMINISTRATION :

There is no fixed dosage regimen for the management of hyperglycaemia in patients with type 2 diabetes with metformin or any other pharmacologic agent. Dosage of Metformin must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily dose. The maximum recommended daily dose of metformin extended release tablets in adults is 2000 mg/day.

Metformin should generally be given once daily with the evening meal. Metformin should be started at a low dose, with gradual dose escalation, both to reduce gastrointestinal side effects and to permit identification of the minimum dose required for adequate glycaemic control of the patient. During treatment initiation and dose titration (see Recommended Dosing Schedule), fasting plasma glucose should be used to determine the therapeutic response to Metformin and identify the minimum effective dose for the patient.

Thereafter, glycosylated haemoglobin should be measured at intervals of approximately three months. The therapeutic goal should be to decrease both fasting plasma glucose and glycosylated haemoglobin levels to normal or near normal by using the lowest effective dose of Metformin, either when used as monotherapy or in combination with sulphonylurea or insulin.

• CONTRAINDICATIONS :

Metformin is contraindicated in patients with:

1. Renal disease or renal dysfunction (e.g., as suggested by serum creatinine levels ≥ 1.5 mg/dL [males], ≥ 1.4 mg/dL [females] or abnormal creatinine clearance), which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.
2. Congestive heart failure requiring pharmacologic treatment.
3. Known hypersensitivity to metformin.
4. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

Metformin should be temporarily discontinued in patients undergoing radiologic studies involving intravascular administration of iodinated contrast materials, because use of such products may result in acute alteration of renal function

PACKAGING INFORMATION :

Metformin 500Strip of 10 tablets

Metformin 850Strip of 10 tablets

Metformin 1000Strip of 10 tablets

• 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.





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).

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, therefore 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.

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According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East

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The company medicines are present in France, Georgia, Egypt and CIF countries.



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