

MINOR®
1000 mg Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about MINOR

Each tablet of MINOR contains Metformin hydrochloride 1000 mg.

MINOR tablets are for oral use.

Metformin is an oral antihyperglycemic, member of the biguanide class. Metformin decreases endogenous hepatic glucose production, decreases intestinal absorption of glucose and increases peripheral glucose uptake and utilization. Metformin does not produce hypoglycemia.

MINOR is indicated as adjunct to diet to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus.

MINOR can be used as monotherapy or concomitantly with other oral antidiabetics or insulin to improve glycemic control in adults.

MINOR can be of value for the treatment of obese diabetic patients.

MINOR may also be used for the treatment of polycystic ovary syndrome.

The way to take MINOR

Take MINOR as directed by your physician. Do not discontinue the treatment without consulting your doctor.

Dosage of MINOR must be individualized on the basis of both effectiveness and tolerance, while not exceeding the maximum recommended daily doses.

You will probably start with a low dose of the medicine. Your doctor may slowly increase the dose until your blood sugar is better controlled. Take MINOR with meals.

The therapeutic goal should be to decrease both fasting plasma glucose and glycosylated hemoglobin levels to normal or near normal by using the lowest effective dose of MINOR, either when used as monotherapy or in combination with other oral antidiabetics or insulin.

The usual starting dose of MINOR for adults as monotherapy or in association with other oral antidiabetics is 500 mg (half a tablet of 1000 mg) twice a day given with meals.

Dosage increases should be made in increments of 500 mg weekly up to a total of 2000 mg per day given in divided doses (1 tablet of 1000 mg twice per day).

For those patients requiring additional glycemic control, MINOR may be given to a maximum daily dose of 3000 mg per day. Doses above 2000 mg may be better tolerated given three times a day with meals.

The usual starting dose for pediatric patients 10 years of age and older is 500 mg twice a day, given with meals. Dosage increases should be made in increments of 500 mg weekly up to a maximum of 2000 mg per day, given in divided doses.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following cases:

- known hypersensitivity to any of the components
- renal disease or renal dysfunction which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction and septicemia
- congestive heart failure or respiratory failure
- acute or chronic metabolic acidosis, including diabetic ketoacidosis

- during acute stress conditions, such as dehydration, and severe infections susceptible to alter renal function
- lactation

Precautions

- Lactic acidosis is a rare but serious complication that can occur due to metformin accumulation. The reported incidence of lactic acidosis in patients receiving metformin is very low. Reported cases have occurred primarily in diabetic patients with significant renal insufficiency. Signs and symptoms of lactic acidosis include: discomfort, muscle pain, malaise, difficult or fast breathing, extreme tiredness, weakness, nausea, vomiting, abdominal pain, feeling cold, unusual somnolence, low blood pressure or slow heartbeat. Inform your doctor immediately if any of these symptoms or other nonspecific symptoms occur.
- Therapy with this drug should not be initiated in case of active liver disease.
- Because aging is associated with reduced renal function, therapy with this drug should not be initiated in patients 80 years of age and older unless measurement of creatinine clearance demonstrates that renal function is not reduced. Care should be taken in dose selection and should be based on careful and regular monitoring of renal function.
- It is important to adhere to dietary instructions, weight loss and regular exercise because these methods help improve insulin sensitivity.
- It is recommended to monitor regularly blood glucose, glycosylated hemoglobin (HbA1c), renal function, liver function and hematologic parameters.
- Tell your doctor if you plan to have surgery or an x-ray procedure with injection of dye (contrast agent). This drug should be temporarily discontinued at the time of or prior to radiologic studies involving the use of intravascular iodine contrast materials, and withheld for 48 hours subsequent to the procedure and reinstated only after renal function has been re-evaluated and found to be normal.
- Use of this drug should be suspended for any major surgical procedure and should not be restarted until your oral intake has resumed and renal function has been evaluated as normal.
- MINOR alone does not usually cause hypoglycemia, although it may occur when this drug is used in conjunction with oral sulfonylureas and insulin.
- Inform your doctor before using this medication in case of pregnancy or lactation. It is recommended not to use this drug during pregnancy or lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

It is recommended to avoid drinking excessive amount of alcoholic beverages either acute or chronic while treated with this medication.

This drug must be used with caution with amiloride, triamterene, digoxin, morphine, procainamide, quinidine, cimetidine, ranitidine, trimethoprim, vancomycin and nifedipine.

Certain drugs tend to produce hyperglycemia or hypoglycemia and lead to loss of glycemic control. These drugs include: diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, beta-2 sympathomimetics, calcium channel blocking drugs, isoniazid, quinolones and angiotensin converting enzyme inhibitors.

Adverse reactions

The most reported adverse reactions include: nausea, vomiting, diarrhea, abdominal pain, flatulence, dyspepsia and anorexia. These side effects generally go away after you take the medicine for a while. Taking your medicine with meals can help reduce these side effects.

Asthenia, taste disorder, headache, dyspnea, palpitations and decrease in serum vitamin B₁₂ levels have been rarely reported.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature up to 30°C, protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

MINOR, Metformin HCl 1000 mg, pack of 30 tablets

Issue date: 04/2008

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