

PACKAGE LEAFLET: INFORMATION FOR THE USER

Metabet SR 500 mg Prolonged Release Tablets

Metformin Hydrochloride

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious or if you notice any side effects not listed on this leaflet, please tell your doctor or pharmacist.

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1. WHAT IS METABET SR AND WHAT IT IS USED FOR

Metabet SR prolonged release tablets contains the active ingredient metformin hydrochloride. Each tablet contains 500 mg of metformin hydrochloride. Metformin belongs to a group of drugs called biguanides which are used in the treatment of diabetes.

Metabet SR is used for the treatment of Type 2 (non-insulin dependent) diabetes mellitus particularly in overweight patients, where diet and exercise changes alone have not been sufficient to control it. In type 2 diabetes, there is too much sugar (glucose) in your blood because your pancreas does not produce enough insulin or because it produces insulin that does not work properly.

Your doctor can prescribe Metabet SR for you to take on its own, or in combination with other oral antidiabetic medicines, or insulin.

2. BEFORE YOU TAKE METABET SR

Do not take Metabet SR

- if you are allergic (hypersensitive) to metformin or to any of the ingredients in this medicine.
- if you have ketosis (this is a symptom of uncontrolled diabetes in which substances called "ketone bodies" accumulate in the blood), you may notice that your breath has an unusual, fruity odour.
- if you have had serious complications with your diabetes or other serious conditions which resulted in rapid weight loss, nausea, vomiting or dehydration and you have fainted or suffered a coma due to your diabetes.
- if you have any problems with your liver or kidneys.
- if you are suffering from severe infection or have recently suffered a severe injury.
- if you have been treated for heart problems or have recently had a heart attack or have problems with your circulation (e.g. frequent cramp in your calves or leg ulcers that do not heal) or breathing difficulties.
- if you are pregnant or breast-feeding.
- if you are likely to have surgery or a scan or an X-ray.
- if you drink alcohol.
- if you are under the age of 18 years.

Take special care with Metabet SR

If you have diabetes you should have your blood or urine tested for sugar regularly. You should return to your doctor at least once a year to check the function of your kidneys (more often if you are elderly or if you have kidney problems). Your doctor may also perform these tests when starting treatment for high blood pressure.

If you have kidney failure, blood levels of metformin can increase, which can very rarely cause lactic acidosis. This results in breathing problems, muscle pains or loss of consciousness and if not treated this can be very dangerous so needs urgent hospital attention. In this case you must contact your doctor immediately or go to the nearest hospital accident and emergency department.

You should avoid drinking alcohol and using alcohol containing medicines as this will increase the risk of lactic acidosis.

If you need to have an X-ray examination tell your doctor that you take Metabet SR as you may need to stop taking it for few days afterwards.

Tell your doctor if surgery is planned. Treatment with Metabet SR should be stopped 2 days before surgery until at least 2 days following surgery.

You should continue your diet during treatment with Metabet SR with an even intake of carbohydrate over the day. If you are overweight continue your energy-restricted diet under medical supervision.

Taking Metabet SR alone does not normally cause low blood sugar levels (hypoglycaemia). Taking Metabet SR in combination with medicines called sulphonylureas, insulin or other treatments for diabetes may cause low blood sugar levels with symptoms such as sweating, fainting, dizziness or weakness, so in this case you should take extra care when driving or operating machinery.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

The effects of Metabet SR may be altered by;

- Steroids such as prednisolone, mometasone, beclometasone
- Beta-2-agonist such as salbutamol used for asthma
- Diuretics (water tablets) such as bendroflumethiazide
- ACE inhibitors such as lisinopril, enalapril used for blood pressure

Taking Metabet SR with food and drink

The tablets should be swallowed whole with a glass of water during or after meals. This can reduce some side effects. Avoid drinking alcohol while taking Metabet SR.

Pregnancy and breast-feeding

Do not take Metabet SR if you are pregnant or breast feeding. Tell your doctor immediately if think you are pregnant.

Driving and using machines:

Metabet SR does not affect your ability to drive vehicles or handle machinery, but if you are also taking other anti-diabetic medicines it is possible that you may feel faint, dizzy or weak. If this happens you should not drive or operate any machinery until you have recovered.

3. HOW TO TAKE METABET SR

Always take Metabet SR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose in:

Adults: The usual starting dose is one 500 mg tablet daily with your evening meals. After two weeks your doctor may increase the dose to a maximum of 2000 mg per day. In some cases, your doctor may recommend that you take the tablet twice a day. Always take the tablets with food and swallow whole (without chewing or breaking), with a glass of water.

Children and adolescents below 18 years: The use of the medication is not recommended.

Your doctor will test your blood glucose and your kidney function at intervals while you are taking Metabet SR to make sure you are taking the right dose. This is especially important when you start taking other new medicines at the same time as Metabet SR.

If you take more Metabet SR than you should

Tell your doctor or contact the nearest hospital, taking the medicine or this leaflet with you. If the overdose is large, "lactic acidosis" is more likely and this is a medical emergency requiring treatment in hospital.

If you forget to take Metabet SR

Take the missed dose as soon as you remember, unless it's nearly time for the next one. Do not take a double dose to make up a forgotten dose. Take the remaining doses at the correct time.

If you stop taking Metabet SR

If you stop taking Metabet SR, tell your doctor as soon as possible, as your diabetes will not be controlled.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Metabet SR can cause side effects, although not everybody gets them.

If you start to lose weight unexpectedly, feel sick with stomach pains, have rapid uncontrolled breathing, or start to lose consciousness, you should stop taking the drug and contact your doctor **immediately** on go to the nearest hospital accident and emergency department. These can be signs of very rare condition called "lactic acidosis" which can be dangerous and needs urgent hospital attention.

The following side effects have also been reported:

Very common (affecting more than one person in 10):

- Stomach pains or stomach upsets such as nausea, vomiting, diarrhoea, loss of appetite. These effects usually get better spontaneously and you should continue to take the tablets. If these do not get better after a few days, tell your doctor.

Common (affecting less than one person in 10 but more than one person in 100):

- Taste disturbance.

Very rare (affecting less than one in 10,000):

- Skin rash (redness and itching of the skin, hives).
- Liver problems (hepatitis), possibly with jaundice (yellowing of skin and eyes) which goes away on stopping Metabet SR.
- A decrease in vitamin B12 absorption, which can result in anaemia, sore tongue, tingling and numbness.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE METABET SR

Keep out of the reach and sight of children. Do not take Metabet SR after the expiry date printed on the blister pack and carton. The expiry date (EXP) refers to the last day of that month

Do not store above 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Metabet SR contains

The active substance is metformin hydrochloride. Each prolonged release tablet contains 500 mg of metformin hydrochloride. The other ingredients in the tablets are Stearic Acid, Shellac (Refined bleached), Povidone K-30, Silica Colloidal Anhydrous, Magnesium Stearate, Hypromellose, Hydroxy Propyl cellulose, Titanium Dioxide, Propylene Glycol, Macrogol 6000, and Talc.

What Metabet SR looks like and contents of the pack

Metabet SR 500 mg tablets are off-white coloured, oval, biconvex, film coated tablets plain on both sides.

Metabet SR is available in blister packs of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90, 100 and 112 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder:

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115 Narborough Road
Leicester, LE3 0PA
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Site responsible for batch release:

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