

MacroBID® 100mg Prolonged-release Capsules

Nitrofurantoin

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again. If you have any further questions, 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The product is known by the name above but will be referred to as MacroBID throughout the rest of this leaflet.

In this leaflet:

1. What MacroBID is and what it is used for
2. Before you take MacroBID
3. How to take MacroBID
4. Possible side effects
5. How to store MacroBID
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1. WHAT MacroBID IS AND WHAT IT IS USED FOR

Nitrofurantoin (the active substance in MacroBID) is an antibiotic.

It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract.

2. BEFORE YOU TAKE MacroBID

DO NOT TAKE MacroBID and talk to your doctor if:

- you are allergic (causing itching, reddening of the skin or difficulty in breathing) to Nitrofurantoin or any of the ingredients of MacroBID (see Section 6 below) or other medicines containing nitrofurantoin
- you have a disease of the kidneys which is severely affecting the way they work (ask your doctor if you are not sure)
- you are in the final stages of pregnancy (labour or delivery) as there is a risk that it might affect the baby
- you have porphyria (blood disorder)
- in patients with G6PD (glucose-6-phosphate dehydrogenase) deficiency
- in infants under three months of age
- you are breast feeding a baby with suspected or known deficiency in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).

Tell your doctor if you are not sure about any of the above.

TAKE SPECIAL CARE with MacroBID and speak to your doctor or pharmacist before taking the capsules if:

- you have diabetes
- you are suffering from any illness causing severe weakness
- you have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness); a lack of vitamin B or abnormal levels of salts in your blood (your doctor will be able to advise you).

The above conditions may increase the chance of developing a side effect which causes damage to the nerves, altered sense of feeling, like pins and needles.

- you lack an enzyme (body chemical) called glucose-6-phosphate dehydrogenase, which causes your red blood cells to be more easily damaged (this is more common in black people and people of Mediterranean, Middle Eastern or Asian origin. Your doctor will know)
- you have any disease of the lungs, liver or nervous system. If you need to take MacroBID for a number of months, your doctor may want to regularly check how your lungs and liver are working
- you have false positive results on testing your urine for glucose
- you have urine coloured yellow or brown.

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. If they are taken with MacroBID their effect or the effect of MacroBID may be changed.

- Antacids for indigestion (e.g. magnesium trisilicate)
- Medicines for gout (e.g. probenecid or sulfinpyrazone)
- Medicines for raised pressure in the eye (glaucoma), such as carbonic anhydrase inhibitors (e.g. acetazolamide)
- Medicines which make the urine less acidic (e.g. potassium citrate mixture)
- Medicines for infections, known as quinolones
- Oral contraceptive "the pill". You will need to use extra contraceptive precautions such as using a condom, as antibiotics can make the contraceptive pill less effective
- Typhoid vaccine, which is given for the prevention of typhoid.

If you are in doubt about any of these medicines ask your doctor or pharmacist.

Taking MacroBID with food and drink:

MacroBID capsules should be taken at meal times with food or milk. This will help to avoid stomach upset and also to help the absorption.

Pregnancy and breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine. As far as it is known MacroBID may be used in pregnancy. However it should not be used during labour or delivery because there is a possibility that use at this stage may affect the baby. If you want to breast feed, please consult with your doctor first.

Driving and using machines:

MacroBID may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected this way until such symptoms go away.

Important information about some of the ingredients in MacroBID:

This medicine contains lactose and sucrose (sugars). If you have been told by your doctor that you are intolerant to some sugars and have to avoid them, contact your doctor before taking this medicine.

3. HOW TO TAKE MacroBID

Follow your doctor's instructions exactly and complete the course of treatment even if you feel better. You should check with your doctor or pharmacist if you are not sure. Do not forget to take your medicine. Capsules should be swallowed whole.

Adults and children over 12 years old:

The normal dosage depends on the type of infection you have and instructions should be written on the label provided by the pharmacist. Consult your pharmacist or doctor if these instructions are not clear.

The usual doses are:

- For treatment of bladder infections: One capsule twice a day for seven days
- For prevention of bladder infections during surgery: One capsule twice a day on the day of the operation and three days thereafter.

MacroBID is not recommended for children under 12 years of age.

MacroBID should be taken with food or milk.

Medical Checks:

Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system. MacroBID may interfere with the results of some tests for glucose in the urine.

If you TAKE MORE MacroBID than you should:

Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any left over capsules with you, as well as the container and label, so that the medical staff know what you have taken.

If you FORGET TO TAKE MacroBID:

Do not worry. If you remember later on that day, take that day's dose as usual. If you miss a whole day's dose take the normal dose on the next day. Do not take a double dose to make up for a forgotten capsule. If you are not sure ask your doctor or pharmacist.

If you STOP TAKING MacroBID:

Your doctor will tell you how long to take the treatment. Do not stop earlier than you are told, even if you feel better.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, MacroBID can cause side effects, although not everybody gets them. Most of them are mild and disappear when you stop taking MacroBID. If you experience any of the side effects detailed below or any other side effects, stop taking MacroBID and consult your doctor.

All medicines can cause allergic reactions although serious allergic reactions are rare. If you notice any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) STOP TAKING your medicine and go to a doctor immediately.

Please note that while taking MacroBID your urine may become coloured dark yellow or brown. This is quite normal and not a reason to stop taking the medicine.

If you notice any of the following side effects consult you doctor immediately:

- Your lungs may react to MacroBID. This may develop quickly, within a week of starting treatment or very slowly, especially in elderly patients. This may produce fever, chills, cough and shortness of breath
- MacroBID may cause the liver to become inflamed, producing jaundice (yellowing of the skin or whites of the eyes).

Other side effects are:

- Feeling sick (nausea) and headache
- Loose stools
- Loss of appetite, stomach ache, and being sick (vomiting)
- Dizziness, drowsiness
- Blood cells have been affected in some patients. This may result in bruising, delayed clotting of the blood, sore throat, fever, anaemia, and a susceptibility to colds or persistent cold
- The nerves outside the spinal cord may be affected causing changes to the sense of feeling and the use of muscles. In addition headache, extreme changes of mood or mental state, confusion, weakness, blurred vision may occur. These effects may be severe and in some instances permanent
- A variety of skin rashes or reactions have occurred in some patients. These may appear as flaking skin, a red rash or fever accompanied by rapid heart rate and severe rash with blistering. Other reactions may include inflammation of salivary glands (causing facial pains), inflammation of the pancreas gland (causing severe abdominal pain) and joint pains.
- Short-term hair loss
- Raised pressure in the skull (causing severe headaches)
- Urinary infection by germs which are not sensitive to MacroBID.

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.

Remember:

This medicine is only for you. Only a doctor can prescribe it for you. Never give this medicine to someone else. It could harm them, even if their symptoms seem the same as yours.

5. HOW TO STORE MacroBID

Keep this medicine out of the sight and reach of children.

Do not store above 30°C (aluminium/aluminium). Do not store above 25°C (For PVC/polyethylene/aclar/aluminium blisters). Store in the original package to protect from light and moisture.

Do not use MacroBID after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 MacroBID contains:

The active substance is 100mg nitrofurantoin in each capsule.

The other ingredients are talc, corn starch, lactose, carbopol, povidone, sugar and magnesium stearate. The capsule shell contains gelatin, quinoline yellow (E104), titanium dioxide (E171) and FD&C Blue No.2 (E132). The printing ink contains shellac, propylene glycol (E1520), titanium dioxide (E171) black iron oxide (E172), ammonium hydroxide (E527) and simethicone.

What MacroBID looks like and contents of the pack:

Appearance: The 100mg capsule has an opaque blue cap and opaque yellow body and bears the monogram "GS 100".

Packaging: The capsules are available in blister strips of 14.

Marketing Authorisation Holder:

Mercury Pharmaceuticals Ltd, No. 1 Croydon, 12-16 Addiscombe Road, Croydon CR0 0XT, UK

Manufacturer:

Custom Pharmaceuticals Limited, Conway Street, Hove, East Sussex, BN3 3LW, UK

This leaflet was last revised in August 2012.

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