

Package leaflet: Information for the user
MacroBID® 100 mg prolonged-release capsules
(nitrofurantoin)

1000152557-001-01

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet:

1. What MacroBID is and what it is used for
2. What you need to know before you take MacroBID
3. How to take MacroBID
4. Possible side effects
5. How to store MacroBID
6. Contents of the pack and other information

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. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MacroBID

DO NOT TAKE MacroBID:

- if you are allergic to Nitrofurantoin, other nitrofurans or any of the other ingredients of this medicine (listed in section 6)
- if you have a disease of the kidneys which is severely affecting the way they work (ask your doctor if you are not sure)
- if you are in the final stages of pregnancy (labour or delivery) as there is a risk that it might affect the baby
- if you have porphyria (blood disorder)
- if in patients with G6PD (glucose-6-phosphate dehydrogenase) deficiency
- if in infants under three months of age
- if 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking MacroBID:

- if you have diabetes
- if you are suffering from any illness causing severe weakness
- if 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)
- if you have a history of allergic reactions
- if you have any problems with your kidneys
- if you have disease of the lungs.

This medicine can also cause lung disease in patients with no previous medical history affecting their lungs. Lung disease can occur in patients on short-term or long-term treatment. Talk to your doctor if you experience trouble breathing, shortness of breath, a lingering cough, coughing up blood or mucus, or pain or discomfort when breathing. These may be symptoms of side effects affecting the lungs.

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.

- if 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)
- if 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

- if you have false positive results on testing your urine for glucose
- if you have urine coloured yellow or brown.
- if you experience fatigue, yellowing of the skin or eyes, itching, skin rashes, joint pain, abdominal discomfort, nausea, vomiting, loss of appetite, dark urine, and pale or gray-colored stools. It may be symptoms of liver disorder.

Other medicines and MacroBID:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- 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
 - 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.

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:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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.

MacroBID contains lactose and sucrose

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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

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.

Use in children

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.

Method of administration

Capsules should be swallowed whole.

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 medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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 your 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 associated with pneumonia. Scarring due to damaged lung tissue may occur
- MacroBID may cause the liver to become inflamed, producing jaundice (yellowing of the skin or whites of the eyes)
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely
- Blue or purple coloration of the skin due to low oxygen levels. A condition known as cyanosis
- Symptoms of fever, flu, abdominal pain, diarrhea, blood in your stool and weakness. These could be signs of a condition known as cutaneous vasculitis
- Symptoms of fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as hepatitis. In rare cases, it may cause liver failure which may be fatal.

Other side effects are:

Rare: may affect up to 1 in 1,000 people

- Loss of consciousness (collapse)
- Damage to bone marrow causing deficiency of the red blood cells (Anaemia).

Not known: frequency cannot be estimated from the available data

- Feeling sick (nausea) and headache
- Loose stools
- Loss of appetite, stomach ache, and being sick (vomiting)
- Diarrhea
- 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.
- Inflammation of small blood vessel walls, causing skin lesions
- Liver inflammation due to turn of immune system against liver cells
- Inflammation of kidney tissue surrounding tubules, causing renal impairment.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MacroBID

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

Do not store above 25°C.

Store in the original package to protect from light and moisture. Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What MacroBID contains:

Each capsule contains 100 mg of nitrofurantoin (as monohydrate and anhydrous form).

The other ingredients are lactose monohydrate, maize starch, talc, povidone, carbomer, sucrose and magnesium stearate. The capsule shell contains gelatin, sodium lauryl sulfate and colourings quinoline yellow (E104), titanium dioxide (E171) and indigo carmine (E132). The printing ink contains shellac, propylene glycol (E1520), black iron oxide (E172), titanium dioxide (E171), ammonium hydroxide (E527) and simethicone.

What MacroBID looks like and contents of the pack:

MacroBID 100mg capsule has an opaque blue cap and opaque yellow body and bears the monogram "GS 100" in grey ink. The capsules are available in blister strips of 14.

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm UK Ltd., 236 Jubilee House, 3 The Drive, Great Warley, Brentwood, CM13 3FR, UK

For any information about this medicine, please contact the Product Licence Holder on www.orifarm.com/uk

Or phone: (+44) 1923 204333

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Manufactured by Famar A.V.E., 7 Anthousa Avenue, 15344 Anthousa, Attika, Greece

MacroBID 100 mg prolonged-release capsules

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