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.

DO NOT TAKE MacroBID

- If you are allergic to Nitrofurantoin, other medicines containing nitrofurantoin 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 have suffered 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.

Other medicines and MacroBID:

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

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:

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

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

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.
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
- 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.

Other side effects are:

Rare (may affect up to 1 in 1,000 people)
- Loss of consciousness (collapse)
- 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, anemia, 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.

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 MHRA yellow card scheme website: 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 30°C (aluminium/aluminium). Do not store above 25°C (For PVC/polyethylene/aclear/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. CONTENTS OF THE PACK AND OTHER 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:
MacroBID 100mg capsule has an opaque blue cap and opaque yellow body and bears the monogram “GS 100”.
The capsules are available in blister strips of 14.

Marketing Authorisation Holder: Mercury Pharmaceuticals Ltd, Capital House, 85 King William Street, London EC4N 7BL, UK
Manufacturer: Famar A.V.E., 7 Anthousa Avenue, 15344 Anthousa, Attiki, Greece

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