Package leaflet: Information for the patient
MacroBID® 100mg Prolonged-Release Capsules
nitrofurantoin

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

The name of your medicine is MacroBID 100mg Prolonged-Release Capsules.
It will be referred to as MacroBID 100 mg Capsules for ease hereafter.

What is in this leaflet:

1. What MacroBID 100 mg Capsules are and what they are used for
2. What you need to know before you take MacroBID 100 mg Capsules
3. How to take MacroBID 100 mg Capsules
4. Possible side effects
5. How to store MacroBID 100 mg Capsules
6. Contents of the pack and other information

1. What MacroBID 100 mg Capsules are and what they are used for

Nitrofurantoin (the active substance in MacroBID) is an antibiotic.It is used to prevent and treat infections of the bladder and lower urinary tract.

2. What you need to know before you take MacroBID 100 mg Capsules

Do not take MacroBID 100mg Capsules:
• If you are allergic (causing itching, reddening of the skin or difficulty in breathing) to nitrofurantoin or any of the ingredients of this medicine (listed in Section 6)
• If you are allergic to other nitrofuran
• If you have been advised by your doctor that you have a low kidney function (eGFR less than 45ml per minute)
• If you are in labour or delivering your baby or breast-feeding
• If you have acute porphyria (group of blood disorders that affect the nervous system or skin, or both)
• If you lack an enzyme called G6PD (Glucose 6 Phosphate Dehydrogenase), which causes your 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 the patient is an infant under three months of age.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking the capsules:
• If you have symptoms of numbness or weakness in the extremities (peripheral neuropathy)
• If you have any kidney problem (You have an eGFR between 30-44 ml/min as your doctor may consider using this medicine after considering the benefit and risk)
• If you have previously experienced an allergic reaction to a drug
• If you have problem with your blood sugar (diabetes mellitus)
• If you have anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness)
• If the concentration of body salts needs adjustment (electrolyte imbalance) or you lack Vitamin B (particularly folate)
• If you have any disease of the lungs, liver or nervous system (If you need to take MacroBid Capsules for a number of months, your doctor may want to regularly check how your lungs and liver are working)
• If you have diarrhea caused by a bacteria known as Clostridium difficile
• If you are taking any other antibacterial medicines
• If you are taking other medicines listed in the next section.
• 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 100 mg Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Do not take MacroBID 100mg Capsules without talking to your doctor or pharmacist first if you are taking:
• Antacids (eg. magnesium trisilicate)
• Medicines for gout (eg. probenecid or Sulfinpyrazone)
• Medicines for glaucoma: such as carbonic anhydrase inhibitors (eg. acetazolamide)
- These are mild 'water tablets' which are usually prescribed when the pressure in the eye ball is raised (glaucoma)
• Medicines which make the urine less acid (eg. potassium citrate mixture)
• Medicines for infections known as quinolones
• Typhoid vaccine, which is given for the prevention of typhoid
• Medicines which slow the passage of food through the stomach (e.g. atropine, hyoscine).

Medical Checks
Your doctor will watch carefully for any effects on the liver, lungs, blood or nervous system.
MacroBID100mg Capsules may interfere with the results of some tests for glucose in the urine.

MacroBID 100 mg Capsules 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.
MacroBID may be used in pregnancy except at term and during labour and delivery.
This medicine should be avoided in mothers who are breast-feeding.

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

MacroBID100 mg Capsules contains lactose, sucrose and sodium:

This medicine contains lactose and sucrose (sugars). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'

3. How to take MacroBID 100 mg Capsules

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

Method of administration
Take MacroBID 100mg Capsules with food or milk.

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. Typical doses are:
For treatment of bladder infections: One capsule twice a day for seven days.
For prevention of bladder infections due to surgery: One capsule twice a day on the day of the operation and three days thereafter.

Use in children
Children under 12 years of age should not take MacroBID 100mg Capsules.

If you take more MacroBID 100mg Capsules than you should
Consult your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any leftover 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 100mg Capsules
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 100mg Capsules
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 or 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 you doctor immediately:
• A group of blood disorders that affect the nervous system or skin, or both (Acute porphyria)
• 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. 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), fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as drug induced autoimmune hepatitis. In rare cases, it may cause liver failure which may be fatal.
• Raised pressure in the skull (causing severe headaches).
• 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, skin symptoms such as lesions e.g. palpable purpura and petechiae. These could be signs of a condition known as cutaneous vasculitis.

Other side effects include:
Rare: may affect up to 1 in 1,000 people
• Damage to bone marrow causing deficiency of the red blood cells (Anaemia)
• Loss of consciousness (collapse)

Not known: Frequency cannot be estimated from the available data
• 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
• Feeling sick (nausea) and headache
• Diarrhea
• Loose stools
• Loss of appetite, stomach ache, and being sick (vomiting)
• Dizziness, drowsiness
• 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 (psychosis), confusion, weakness, involuntary eye movement (which may cause the eye to rapidly move from side to side, up and down or in a circle, and may slightly blur 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. Cases of a severe form of drug reaction with involvement of skin and other parts of the body (DRESS syndrome) are also reported. 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
• Fatigue, chills and drug fever
• Short-term hair loss

• 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
• MacroBID may interfere with the results of some tests for glucose in the urine

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 HPRA Pharmacovigilance,
Website: www.hpra.ie;

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MacroBID 100mg Capsules
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
Store in the original package in order to protect from light.
Do not store above 25°C.

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 protect the environment.

6. Contents of the pack and other information

What MacroBID 100mg Capsules contains
The active substance is nitrofurantoin. Each prolonged release hard capsule contains 100mg of the active substance (in the anhydrous and monohydrate 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), printing ink includes shellac, propylene glycol (E1520), black iron oxide (E172), titanium dioxide (E171), ammonium hydroxide (E527) and simethicone.

What MacroBID 100mg Capsules looks like and contents of the pack
The 100mg capsule has an opaque blue cap and opaque yellow body and bears the monogram “GS 100”.
The capsules are available in blister packs of 14 capsules and a sample pack of 2 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Amdipharm Limited
Unit 17, Northwood House
Northwood Crescent
Northwood
Dublin 9
D09 V504
Ireland

Manufacturer
Skyepharma Production SAS, Zone Industrielle Chesnes Ouest, 55 rue du Montmurier , Saint Quentin Fallavier , 38070, France

Custom Pharmaceuticals Limited,
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