PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PREVURO 50 (hard gelatine capsules)
Nitrofurantoin 50 mg
Contains sugar: Lactose monohydrate 103,50 mg
PREVURO 100 (hard gelatine capsules)
Nitrofurantoin 100 mg
Contains sugar: Lactose monohydrate 207,00 mg

Read all of this leaflet carefully before you start taking PREVURO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PREVURO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What PREVURO is and what it is used for

Nitrofurantoin the active substance in PREVURO is an antibiotic. It is used to prevent and treat infections of the bladder, kidney and other parts of the urinary tract. It is not meant to treat abscesses (a build-up of pus) of the bladder, kidney and other parts of the urinary tract.

2. What you need to know before you take PREVURO

Do not take PREVURO

- If you are hypersensitive (allergic) to nitrofurantoin or any of the other ingredients of PREVURO.
- If you have a disease of the kidneys (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 suffer from a blood disorder called porphyria.
- If you are deficient in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).
- If your child is under one months of age.

- If you are breastfeeding a baby with suspected or known deficiency in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).

Take special care with PREVURO:

- 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) or 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.
- The above conditions may increase the chance of developing a side effect which results in damage to the nerves, causing altered sense of feeling such as 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.
- If you have any disease of the lungs, liver or nervous system. If you need to take PREVURO 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 grey-coloured stools. It may be symptoms of liver disorder.

Children and adolescents

Do not give PREVURO to children one months old or less.

Other medicines and PREVURO

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor 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.

PREVURO with food, drink and alcohol

PREVURO should be taken at mealtimes with food or milk. This will help to avoid stomach upset and also help absorption of the medicine.

Pregnancy, breastfeeding and fertility

The safety of PREVURO during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking PREVURO.

PREVURO 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 breastfeed, please consult your doctor first.

Driving and using machines

PREVURO may cause dizziness and drowsiness.

It is not always possible to predict to what extent PREVURO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PREVURO affects them.

PREVURO contains lactose

PREVURO contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take PREVURO.

3. How to take PREVURO

Do not share medicines prescribed for you with any other person.

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

The usual dose is:

Adults:

Bladder infections: 50 mg to 100 mg four times a day, with meals and at bedtime.

To prevent recurrences of bladder infections: 50 mg to 100 mg per day.

PREVURO is highly soluble in urine, to which it may cause a brown colour.

If you have the impression that the effect of PREVURO is too strong or too weak, tell your doctor or pharmacist.

If you take more PREVURO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of PREVURO

Do not take a double dose to make up for forgotten individual doses.

If you stop taking PREVURO

Do not stop treatment early. Your doctor will tell you how long your treatment with PREVURO will last.

4. Possible side effects

PREVURO can have side effects.

Not all side effects reported for PREVURO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PREVURO, please consult your healthcare professional for advice.

If any of the following happens, stop taking PREVURO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PREVURO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Your lungs may react to PREVURO. 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.
- PREVURO 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 colouration of the skin due to low oxygen levels. A condition known as cyanosis.
- Symptoms of fever, flu, abdominal pain, diarrhoea, 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- Loss of consciousness (collapse).
- Aplastic anaemia (when you bone marrow cannot make enough new blood cells for your body to work normally).

The following side effects have been reported but the frequency is unknown:

- Feeling sick (nausea) and headache.
- Diarrhoea.
- 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.
- 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.

- Urinary infection by germs which are not sensitive to PREVURO.
- Inflammation of small blood vessel walls, causing skin lesions.
- Liver inflammation due to turn of immune system against liver cells. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
- Inflammation of kidney tissue surrounding tubules, causing renal impairment.
- Jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes).
- Confusion.
- Depression.
- Very happy (euphoria).
- Psychotic reactions.
- Urine may become coloured dark yellow or brown coloured. This is quite normal and not a reason to stop taking the medicine.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PREVURO.

5. How to store PREVURO

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Do not remove the blisters from the outer carton until required for use.
- Store in the original package / container.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PREVURO contains

- The active substance is nitrofurantoin.
- The other ingredients are:

  50 mg capsules: Gelatine, lactose monohydrate, maize starch, talc, titanium dioxide, yellow iron oxide.

  100 mg capsules: Gelatine, lactose monohydrate, maize starch, talc, titanium dioxide, yellow iron oxide.

What PREVURO looks like and contents of the pack

PREVURO 50 mg is a hard gelatine capsule with yellow cap and white body.

PREVURO 100 mg is a hard gelatine capsule with yellow cap and body.

PREVURO are packed in a PVC/aluminium blister of 10 capsules.

Holder of Certificate of Registration and Manufacturer

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PREVURO 100: 57/18.5/0296