APPROVED PATIENT INFORMATION LEAFLET:
RBC PHARMACEUTICALS (PTY) LTD.
RENOFTRA 100 (Nitrofurantoin microcrystals, Capsules)

SCHEDULING STATUS:

S4

RENOFTRA 100 (Hard gelatin capsules)

Nitrofurantoin

Contains sugar: Lactose Monohydrate 234 mg.

Read all of this leaflet carefully before you start taking RENOFTRA 100.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RENOFTRA 100 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 RENOFTRA 100 is and what it is used for.

Nitrofurantoin (the active substance in RENOFTRA 100) 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 are given RENOFTRA 100.

Do not take RENOFTRA 100 if:

- You are allergic to nitrofurantoin or any of the ingredients of RENOFTRA 100 (listed in Section 6)
- 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 suffer from a blood disorder called porphyria.
- You are deficient in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).
- Your child is under one 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.

Warnings and precautions

Talk 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); or a lack of vitamin B or abnormal levels of salts in your blood (your doctor will be able to advise you).
- You have a history of allergic reactions.
- 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, causes altered sense of feeling, 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).

- 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.

- You have any disease of the liver or nervous system. If you need to take RENOFTRA 100 for a longer period, your doctor may want to regularly check how your liver is working.
- As this medicine may interfere with urine tests for glucose, causing the test to give a "false positive" result. That is, the test may say that glucose is present in the urine even if it is not. This medicine may also cause your urine to turn yellow or brown.
- 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 RENOFTRA 100

Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary, over-the-counter traditional medicines).

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 RENOFTRA 100 their effect or the effect of RENOFTRA 100 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 which slow the passage of food through the stomach (e.g., atropine, hycosine);
- 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. RENOFTRA 100 may interfere with the results of some tests for glucose in the urine.

Pregnancy, breastfeeding and fertility

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 any medicine. As far as it is known RENOFTRA 100 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 your doctor first.

Driving and using machines

RENOFTRA 100 may cause dizziness and drowsiness. You should not drive or operate machinery if you are affected this way until such symptoms go away.

RENOFTRA 100 contains lactose monohydrate

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

3. How to take RENOFTRA 100

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

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

Adults:

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 urinary infection: One 50 mg or 100 mg capsule four times a day for seven days with meals and at bedtime.
- Prevent recurrences: One 50 mg or 100 mg capsule per day.

Children:

The dose depends on the weight of the child and will be provided by your doctor. Follow your doctor's instructions exactly.

Children below one month of age should not take RENOFTRA 100

Method of Administration

RENOFTRA 100 should always be taken with food or milk. Taking this medicine with food or milk makes it work more effectively. This will help to avoid stomach upset and also to help the absorption. Your doctor will tell you how long your treatment with RENOFTRA 100 will last. If you have the impression that the effect of RENOFTRA 100 is too strong or too weak, tell your doctor or pharmacist.

If you take more RENOFTRA 100 than you should

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

If you forget to take RENOFTRA 100:

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 RENOFTRA 100:

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:

RENOFTRA 100 can have side effects.

Not all side effects reported for RENOFTRA 100 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RENOFTRA 100, please consult your health care provider for advice.

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 as you may have had a serious reaction to RENOFTRA 100. You may need urgent medical attention or hospitalisation.

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

- Problems with your lungs. This can happen quickly, within one week after the start of treatment, or very slowly, especially in the elderly and can lead to fever, shivering, coughing and shortness of breath associated with pneumonia and/or tissue damage.
- Jaundice (inflammation of the liver causing yellowing of the skin or whites of the eyes).
- 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.
- Raised pressure in the skull (causing severe headaches).
- 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, diarrhoea, blood in your stool and weakness. These could be signs of a condition known as cutaneous vasculitis
- Symptoms of jaundice, fatigue, abdominal pain, joint pain and swelling. These could be signs of a condition known as autoimmune hepatitis.

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

Please note that while taking RENOFTRA 100 your urine may become dark yellow or brown coloured. This is quite normal and not a reason to stop taking the medicine.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Body stop producing enough red blood cells.
- Loss of consciousness (collapse).

Frequency unknown side effects:

- 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.
- 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 (causing severe abdominal pain) and joint pains.
- Short-term hair loss.
- Urinary infection by germs which are not sensitive to RENOFTRA 100.
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. 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 RENOFTRA 100.

5. How to store RENOFTRA 100

Store at or below 30 °C and protected from light.

Keep the blisters in the carton until required for use.

The storage of RENOFTRA 100 will not be your responsibility.

6. Contents of the pack and other information

What RENOFTRA 100 contains:

The active substance is Nitrofurantoin. RENOFTRA 100 are available in two strengths, containing 100 mg nitrofurantoin. The other ingredients are

Lactose Monohydrate

Corn Starch

Talc

What RENOFTRA 100 looks like and contents of the pack:

Capsules

Blue opaque cap and blue opaque body, hard gelatin size “2” capsules imprinted with “LS” on cap and “412” on body with black ink containing light yellow to yellow colored powder.

Packaging: 28 capsules in a carton. The capsules are available in blister packs of 14 capsules (2 X 14s).

REGISTRATION NUMBER

59/18.5/0553

Holder of Certificate of Registration

RBC PHARMACEUTICALS (PTY) LTD.

23 Kiaat Street, ERF 926, Extension 7,

Noordwyk, Midrand, Gauteng,

South Africa, 1687

This leaflet was last revised on:

Date of registration: 26 May 2026

Date of the most recent revision: TBA

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

RBC PHARMACEUTICALS (PTY) LTD. Tel: +27 10 224 0999

Other sources of information

Detailed information on this medicine is available on the RBC PHARMACEUTICALS (PTY) LTD web site: http://www.rbcpharma.com