PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NITROFURANTOIN 50 PHARMC, 50 mg hard capsules

NITROFURANTOIN 100 PHARMC, 100 mg, hard capsules

Nitrofurantoin

Contains sugar:

NITROFURANTOIN 50 PHARMC: Lactose monohydrate 113 mg per capsule

NITROFURANTOIN 100 PHARMC: Lactose monohydrate 226 mg per capsule

Read all of this leaflet carefully before you start taking NITROFURANTOIN PHARMC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- NITROFURANTOIN PHARMC 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 NITROFURANTOIN PHARMC is and what it is used for
2. What you need to know before you take NITROFURANTOIN PHARMC
3. How to take NITROFURANTOIN PHARMC
4. Possible side effects
5. How to store NITROFURANTOIN PHARMC
6. Contents of the pack and other information

1. What NITROFURANTOIN PHARMC is and what it is used for

Nitrofurantoin (the active substance in NITROFURANTOIN PHARMC capsules) 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 NITROFURANTOIN PHARMC

Do not take NITROFURANTOIN PHARMC:

- If you are hypersensitive (allergic) to nitrofurantoin or any of the other ingredients of NITROFURANTOIN PHARMC (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 suffer from a blood disorder called porphyria.
- If you are deficient in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).
- If you are breast feeding a baby with suspected or known deficiency in an enzyme called G6PD (glucose-6-phosphate dehydrogenase).

Warnings and precautions

Take special care with NITROFURANTOIN PHARMC:

- If you have problems with your lungs, e.g. asthma or a history of asthma attacks, chronic obstructive pulmonary disease (COPD), lung cancer, abnormal build-up of fluid in the lungs, lung infections.
- If you have liver impairment.
- If you have neurological disorders, e.g. epilepsy, Alzheimer disease and other dementias, cerebrovascular diseases including stroke, migraine and other headache disorders, multiple sclerosis, Parkinson's disease, brain tumours, or traumatic disorders of the

nervous system due to head trauma.

- 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.

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.

- 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 frequent 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 NITROFURANTOIN PHARMC for a number of months, your doctor may want to regularly check how your lungs and liver are working.

Other medicines and NITROFURANTOIN PHARMC

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

Especially tell your doctor if you are taking any of the following:

- 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, hyoscine).
- 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, oxolinic acid or nalidixic acid.
- Oral contraceptive “the pill”. You will need to use extra contraceptive precautions such as using a condom, as antibiotics can make the contraceptive pill less effective.
- Typhoid fever vaccine, which is given for the prevention of typhoid.

If you are in doubt about any of these medicines, ask your doctor or pharmacist.

NITROFURANTOIN PHARMC may interfere with the results of some tests for glucose in the urine.

NITROFURANTOIN PHARMC with food and drink

NITROFURANTOIN PHARMC capsules should be taken at mealtimes with food or milk. This will help to avoid stomach upset and also to help the absorption.

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

The safe use during early pregnancy has not been established. NITROFURANTOIN PHARMC 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

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

NITROFURANTOIN PHARMC contains lactose monohydrate

NITROFURANTOIN PHARMC contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NITROFURANTOIN PHARMC.

3. How to take NITROFURANTOIN PHARMC

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

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

Adults

For treatment of infections: Either one 50 mg capsule or one 100 mg capsule four times a day for seven days with meals and at bedtime.

For prevention of further infections: Either one 50 mg capsule or one 100 mg capsule at bedtime

For prevention of infections during surgery: One 50 mg capsule four times a day on the day of the operation and three days thereafter.

Children and infants over one month of age:

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

Your doctor will tell you how long your treatment with NITROFURANTOIN PHARMC will last.

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

Capsules should be taken with food or milk.

Your doctor will watch carefully for any effects on the liver, lungs, blood, or nervous system.

If you take more NITROFURANTOIN PHARMC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. If you take too much NITROFURANTOIN PHARMC, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions.

If you forget to take NITROFURANTOIN PHARMC

If you forget to take a dose, take it as soon as you remember. 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 stop taking NITROFURANTOIN PHARMC

Your doctor will tell you how long to take the treatment. Do not stop earlier than you are told, even if you feel better.

4. Possible side effects

NITROFURANTOIN PHARMC can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (collapse).

These are all very serious side effects. If you have them, you may have had a serious reaction to NITROFURANTOIN PHARMC. 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 NITROFURANTOIN PHARMC. 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.
- 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).

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

Tell your doctor if you notice any of the following:

Frequency unknown

- feeling sick (nausea) and headache,
- loose stools,
- loss of appetite, stomach ache, and being sick (nausea and 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 NITROFURANTOIN PHARMC.

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

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 or pharmacist. 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.

In addition, side effects can also be reported to info@pharmacorp.co.za. By reporting side effects, you can help provide more information on the safety of NITROFURANTOIN PHARMC.

5. How to store NITROFURANTOIN PHARMC

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep the blisters in the outer carton until required for use.
- 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 NITROFURANTOIN PHARMC contains

- The active substance is nitrofurantoin.

NITROFURANTOIN 50 PHARMC

Each hard gelatin capsule contains 50 mg of nitrofurantoin macrocrystals.

Contains sugar: lactose monohydrate 113 mg per tablet.

NITROFURANTOIN 100 PHARMC

Each hard gelatin capsule contains 100 mg of nitrofurantoin macrocrystals.

Contains sugar: lactose monohydrate 226 mg per tablet.

- The other ingredients are:

Capsule fill contents

Lactose monohydrate, maize starch, talc (E553b).

Capsule shell

Gelatin, iron oxide yellow (E104), sodium lauryl sulphate, titanium dioxide (E171).

Printing ink

Black iron oxide (E172), shellac (E904).

What NITROFURANTOIN PHARMC looks like and contents of the pack

NITROFURANTOIN 50 PHARMC

Hard gelatin capsule size ‘3’ with “A9” imprint on opaque yellow cap and plain opaque white body containing pale yellow granular powder.

NITROFURANTOIN 100 PHARMC

Hard gelatin capsule size ‘2’ with “A8” imprint on opaque yellow cap and plain opaque yellow body containing pale yellow granular powder.

Contents of the pack

10 capsules are packed in a blister strip of aluminium foil with VMCH coating (25 micron) and PVC white opaque film (250 micron). 3 or 5 blister strips are packaged in a cardboard box along with a leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

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NITROFURANTOIN 100 PHARMC: 55/18.5/0863

Access to the corresponding Professional Information

(and the translated Patient Information Leaflet)

www.pharmacorp.co.za