

**PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **Nitrofurantoin CNX Therapeutics 100 mg 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 or pharmacist.
- 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Nitrofurantoin CNX Therapeutics 100 mg prolonged-release capsules but it will be referred to as Nitrofurantoin CNX throughout this leaflet.

#### **What is in this leaflet**

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

#### **1. What Nitrofurantoin CNX is and what it is used for**

Nitrofurantoin (the active substance in Nitrofurantoin CNX Therapeutics 100mg prolonged-release 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 do you need to know before you take Nitrofurantoin CNX**

##### **Do not take Nitrofurantoin CNX**

- if you are allergic to nitrofurantoin, other nitrofurans 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 you have G6PD (glucose-6-phosphate dehydrogenase) deficiency
- do not use 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 or pharmacist before taking Nitrofurantoin CNX:

- if you have diabetes
- if you are suffering from any illness causing severe weakness

#### **Medical Checks**

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

### **Children**

This medicine is not suitable for children under 12 years of age.

### **Other medicines and Nitrofurantoin CNX**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and other medicines you've bought without a prescription.

Some of these medicines can change the effect of Nitrofurantoin CNX.

- antacids containing magnesium trisilicate may reduce the absorption of nitrofurantoin.
- tell your doctor if you are taking an anti-gout medicine such as probenecid and sulfinpyrazone. Some of these medicines can reduce the effect of Nitrofurantoin CNX.
- if you are prescribed a quinolone antibacterial medicine, tell the doctor that you are also taking this medicine. Combining these medicines can reduce the effectiveness of both.
- carbonic anhydrase inhibitors (such as acetazolamide for the treatment of glaucoma).
- the oral typhoid vaccine may not work when you are taking this medicine. Discuss this with your doctor.
- urine glucose tests can be affected by this medicine.

If you are not sure about any of these medicines, consult your doctor or pharmacist.

### **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.

### **Pregnancy**

As far as it is known, nitrofurantoin may be used during pregnancy. However, this medicine should not be used during labour and delivery because there is a possibility that use at this stage may affect the baby. Always follow your doctor's instructions carefully.

### **Breast-feeding**

If you wish to breastfeed, consult your doctor first because this medicine passes into breast milk and may be harmful to infants under 3 months of age.

### **Driving and using machines**

This medicine may cause dizziness and drowsiness (sleepiness). You should not drive or operate machinery if you are affected this way until such symptoms go away.

### **Nitrofurantoin CNX contains lactose and sucrose**

This medicine contains lactose and sucrose which are types of sugars. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## **3. How to take Nitrofurantoin CNX**

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.

### **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.

The usual doses are:

- For treatment of bladder infections: One capsule twice a day for seven days

- For prevention of bladder infections during surgery: One capsule twice a day on the day of the operation and three days thereafter.

### **Method of administration**

Nitrofurantoin CNX is to be taken by mouth: the capsule should be swallowed whole, with a meal or with some milk or yogurt. Thus, this medicine is better tolerated and gastrointestinal (stomach and intestines) reactions are minimized.

### **If you take more Nitrofurantoin CNX than you should**

Contact your doctor or pharmacist immediately or go to the emergency department of the nearest hospital. Always take any remaining capsules with you, as well as the container and label, so that the medical staff know what you have taken. Vomiting and stomach problems may occur when you take too much of this medicine.

### **If you forget to take Nitrofurantoin CNX**

Normally you should take one capsule twice a day. If you miss a dose, take it as soon as possible. If it is almost time for the next dose, skip the forgotten dose and go back to your regular schedule. Do not take a double dose to make up for a forgotten capsule.

If you have forgotten several doses in a row, please contact your doctor. He will probably prescribe a new treatment.

### **If you stop taking Nitrofurantoin CNX**

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 stop the treatment too soon, the symptoms may return very quickly and this may be undesirable and unpleasant for you. That is why it is important that you complete the treatment.

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 Nitrofurantoin CNX.

**All medicines can cause allergic reaction 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 this medicine and go to a doctor immediately.**

If you experience any of the side effects detailed below stop taking Nitrofurantoin CNX and consult your doctor.

- 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.
- 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, 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.
- 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.

Other side effects include:

**Rare (may affect up to 1 in 1,000 people)**

- Loss of consciousness (collapse)
- Blue or purple coloration of the skin due to low oxygen levels. A condition known as cyanosis.
- Severe reduction in blood cells which can cause weakness, bruising or make infections more likely. A condition known as aplastic anaemia.

**Not known (frequency cannot be estimated from the available data)**

- Feeling sick (nausea) and headache
- Diarrhoea
- Loss of appetite, stomach ache, and being sick (vomiting)
- Dizziness, drowsiness (sleepiness)
- 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 Nitrofurantoin CNX
- 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
- 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 any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://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 Nitrofurantoin CNX**

Keep this medicine out of the sight and reach of children.

Do not store above 25 °C.

Do not use this medicine after the expiry date (EXP) which is stated on the carton and/or blister. The expiry date refers to the last day of that month.

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 to protect the environment.

**6. Contents of the package and other information**

**What Nitrofurantoin CNX contains**

- The active substance in this medicine is nitrofurantoin. Each prolonged release hard capsule contains equivalent of 100mg nitrofurantoin in the form of nitrofurantoin macrocrystals and nitrofurantoin monohydrate.
- The other ingredients are:

- capsule content: talc, maize starch, carbomers, povidone, lactose monohydrate, sucrose, magnesium stearate.
- capsule shell: iron oxide yellow, iron oxide black, titanium dioxide (E 171), indigo carmine, gelatin.
- printing ink: shellac, propylene glycol (E 1520), strong ammonia solution, water, potassium hydroxide, titanium dioxide (E 171).

**What Nitrofurantoin CNX looks like and contents of the pack**

Nitrofurantoin CNX Therapeutics 100 mg prolonged-release capsules are 19.4 mm long and 6.9 mm wide capsules with blue opaque cap debossed with “NTRF” in white ink and yellow opaque body.

Carton box containing standard PVC-PCTFE/Alu blisters with 2, 6, 7, 14 or 20 capsules each.

Not all pack sizes may be marketed.

**Marketing Authorization Holder**

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