

# **APO-Nitrofurantoin**

nitrofurantoin

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## **Consumer Medicine Information**

**For a copy of a large print leaflet, Ph: 1800 195 055**

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

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

## **What this medicine is used for**

Nitrofurantoin is used to treat infections of the urinary system caused by bacteria, such as bladder infections.

It is an antibiotic which belongs to a group of medicines called nitrofurans. It works by killing or stopping the growth of the bacteria and other organisms causing these infections.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is only with a doctor's prescription.

## **Before you take this medicine**

### **When you must not take it**

**Do not take this medicine if you have an allergy to:**

- any medicine containing nitrofurantoin or any other nitrofuran
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take this medicine if you have or have had severe kidney problems.**

**Do not take this medicine if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not give this medicine to a child under the age of 1 month.**

Safety and effectiveness in children younger than 1 month have not been established.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

**Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- kidney problems
- G-6-PD deficiency, a condition where you lack an enzyme in red blood cells (occurs in a very small number of people of African descent or Mediterranean or Near Eastern origin)
- anaemia (a blood disorder)
- diabetes
- vitamin B deficiency

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

Your doctor can discuss with you the risks and benefits involved.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

## **Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and this one may interfere with each other. These include:

- phenobarbitone, used to treat epilepsy
- medicines used to treat gout, such as probenecid and sulfinpyrazone
- antacids, used to treat heartburn, indigestion or reflux
- agents used to make the urine more acidic, such as ammonium chloride tablets
- agents used to make the urine more alkaline, such as sodium bicarbonate

These medicines may be affected by nitrofurantoin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

**Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.**

## **How to take this medicine**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the directions, ask your doctor or pharmacist for help.**

## **How much to take**

### **Adults**

### **If you already have an infection:**

The usual dose is 1 capsule (either the 50 mg or 100 mg strength) four times daily.

### **To prevent an infection:**

The usual dose is 1 capsule (either the 50 mg or 100 mg strength) taken at night.

### **Children**

The dose for children will depend on their body weight. The usual dose is 1.25 to 1.75 mg/kg of body weight given four times a day. Your doctor will calculate the proper dose considering the age and weight of the child, and how severe the infection is.

### **How to take it**

**Swallow the capsules with a full glass of water.**

### **When to take it**

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

**Take your medicine immediately after food or a glass of milk.**

If taken on an empty stomach it may cause a stomach upset.

## **How long to take it**

**Continue taking your medicine until you finish the bottle or until your doctor recommends.**

**Do not stop taking your medicine earlier than this, even if you are feeling better.**

Check with your doctor if you are not sure how long you should be taking the medicine.

## **If you forget to take it**

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

## **If you take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go**

**to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.**

**You may need urgent medical attention.**

## **While you are using this medicine**

### **Things you must do**

**Tell your doctor if the symptoms of your infection do not improve, or if they become worse.**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

**It may affect other medicines used during surgery.**

**If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

**If you are about to have any urine or blood tests, tell your doctor that you are taking this medicine.**

**It may interfere with the results of some tests.**

**Keep all your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

## **Things you must not do**

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine before you finish the bottle or until as advised by your doctor, even if you are feeling better.**

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or may return.

**Do not take antacid preparations at the same time as this medicine.**

These preparations may affect how well nitrofurantoin works.

## **Things to be careful of**

**When taking this medicine, your urine may turn brown.**

This is temporary and not associated with any serious effects.

**Nitrofurantoin may interfere with the normal production of sperm cells. This is reversible.**

If this causes you any concerns, please speak to your doctor.

## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea and vomiting
- diarrhoea
- headache and dizziness
- drowsiness and altered mood

- feeling weak

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

**Tell your doctor as soon as possible if you notice any of the following:**

- diarrhoea (which may occur up to several weeks after finishing the course)
- numbness or tingling in any area of the body
- confusion, hallucinating or illusions
- hepatitis, an inflammation of the liver which can result in yellowing of the skin and eyes, lower back pain, dark urine, tiredness and a general feeling of being unwell
- fever and chills
- chest pain, difficulty with breathing and cough
- skin rash and itchiness
- asthma attack
- sore throat or gums and a continual feeling of tiredness

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

## **Storage and Disposal**

### **Storage**

**Keep your capsules in the bottle until it is time to take them.**

If you take the capsules out of the bottle, they may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 25°C.**

**Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Disposal**

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **Product description**

### **What it looks like**

APO-Nitrofurantoin is available as 50 mg and 100 mg capsules.

These are supplied in bottles of 4 (50 mg only) or 30 capsules.

### **Nitrofurantoin 50 mg Capsules**

Yellow, opaque cap and white opaque body, size "3" plain, hard gelatin capsule filled with yellow coloured powder.

AUST R 299383.

### **Nitrofurantoin 100 mg Capsules**

Yellow, opaque cap and yellow opaque body, size "2", plain, hard gelatin capsule filled with yellow coloured powder.

AUST R 299385.

## Ingredients

APO-Nitrofurantoin capsules contain either 50 mg or 100 mg of nitrofurantoin macrocrystals as the active ingredient.

This medicine also contains the following:

- pregelatinised maize starch
- purified talc
- lactose monohydrate
- magnesium stearate
- gelatin
- purified water
- titanium dioxide
- quinoline yellow
- sunset yellow FCF
- This medicine is free-from gluten.

## Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Tel: (02) 8877 8333

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