

ARX-NITROFURANTOIN

Nitrofurantoin (macrocrystals) capsule

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking ARX-NITROFURANTOIN.

This leaflet answers some common questions about ARX-NITROFURANTOIN. It does not contain all the available information and 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 expected benefits it will have for you.

Take ARX-NITROFURANTOIN as instructed and follow the advice given in this leaflet.

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 ARX-NITROFURANTOIN is used for

ARX-NITROFURANTOIN is used to treat infections of the urinary system caused by bacteria, for example, bladder infections.

ARX-NITROFURANTOIN 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.

Your doctor may have prescribed ARX-NITROFURANTOIN for another reason.

Ask your doctor if you have any questions about why ARX-NITROFURANTOIN has been prescribed for you.

These medicines are only available with a doctor's prescription.

Before you take ARX-NITROFURANTOIN

When you must not take it

Do not take ARX-NITROFURANTOIN if:

1. **You have an allergy to ARX-NITROFURANTOIN or any other nitrofurantoin, or to any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction include skin rash, itching, difficulty with breathing, fever and chills.**
2. you have severe kidney problems
3. you are pregnant and close to giving birth.

Infants under one month of age should not be given ARX-NITROFURANTOIN.

Do not take ARX-NITROFURANTOIN if the packaging is torn or shows signs of tampering.

Do not take it after the expiry date (EXP) printed on the pack.

Before you start taking it

You must tell your doctor if:

1. You are pregnant or intend to become pregnant. Your doctor will discuss the risks and benefits of taking ARX-NITROFURANTOIN during pregnancy
2. You are breastfeeding or intend to breastfeed. Your doctor will discuss the risks and benefits of taking ARX-

NITROFURANTOIN while breastfeeding.

3. you have or have had any other health problems including:
 - kidney problems
 - if you lack an enzyme in red blood cells (G-6-PD deficiency) which occurs in a very small number of people of African descent, people of Mediterranean and near Eastern origin.
 - anaemia (a blood disorder), diabetes, or vitamin B deficiency.

When taking ARX-NITROFURANTOIN your urine may turn brown. This is temporary and not associated with any serious effects.

ARX-NITROFURANTOIN may interfere with the normal production of sperm cells. This is reversible. If this causes you any concerns, please speak to your doctor.

If you have not told your doctor or pharmacist about any of the above, tell them before you start to take ARX-NITROFURANTOIN.

Taking other medicines

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

There may be interference between ARX-NITROFURANTOIN and some other medicines including:

- phenobarbitone, a medicine used to treat epilepsy
- medicines used to treat gout, such as probenecid and sulfinpyrazone
- antacids, medicines 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 ARX-NITROFURANTOIN or may affect how well they work.

You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking ARX-NITROFURANTOIN.

How to take ARX-NITROFURANTOIN

Your doctor or pharmacist will tell you how to take your medicine. Follow all directions given to you by your doctor or pharmacist carefully. The directions given to you by your doctor or pharmacist on how to take ARX-NITROFURANTOIN may differ from the information contained in this leaflet. You may be given a different dosage depending on your condition or how you react to the medicine. If you do not understand the instructions on the label, 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 taking into account the age and weight of the child and how severe the infection is.

When to take it

ARX-NITROFURANTOIN should be swallowed with or immediately after food or with a glass of milk.

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

How long to take it

Continue taking ARX-NITROFURANTOIN until you finish the given carton pack 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 for 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, then go back to taking your medicine as you would normally.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to the Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much ARX-NITROFURANTOIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers for these services handy. Have the medicine or this leaflet available to give details if needed.

While you are using ARX-NITROFURANTOIN

Things you must do

- If the symptoms of your infection do not improve, or if they become worse, tell your doctor
- If you become pregnant while you are taking ARX-NITROFURANTOIN, tell your doctor
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking ARX-NITROFURANTOIN
- If you have to have any urine or blood tests, tell your doctor you are taking ARX-NITROFURANTOIN. This medicine may affect the results of some laboratory tests
- Tell all doctors, dentists and pharmacists who are treating you that you are taking ARX-NITROFURANTOIN.

Things you must not do

Do not stop taking your medicine before you finish the given carton pack or 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 ARX-NITROFURANTOIN. These preparations may affect how well ARX-NITROFURANTOIN works.

Do not give ARX-NITROFURANTOIN to anyone else, even if they have the same condition as you.

Do not use ARX-NITROFURANTOIN to treat any other medical complaints unless your doctor tells you to.

Side effects

Check with your doctor as soon as possible if you have any problems while taking ARX-NITROFURANTOIN, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like many medicines, ARX-NITROFURANTOIN may cause side effects. If they occur, they are likely to be minor and temporary. However, some may be serious and need medical attention.

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

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

- nausea and vomiting
- diarrhoea
- headache and dizziness
- drowsiness and altered mood
- feeling weak.

Tell your doctor immediately if you notice any of the following:

- swelling of the face, lips, mouth, throat or neck which may cause difficulty with swallowing or breathing
- diarrhoea (which may occur up to several weeks after finishing the course)
- numbness or tingling in any area of the body
- confusion, having hallucinations 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.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking ARX-NITROFURANTOIN

Storage

Keep the medicine in the blister pack until it is time to take it.

If you take the capsules out of the blister, the medicine may not keep well.

Keep the medicine in a cool dry place.

ARX-NITROFURANTOIN must be stored where it stays below 25°C. Do not store ARX-NITROFURANTOIN, or any other medicine in a bathroom or near a sink. Do not leave the medicine in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your ARX-NITROFURANTOIN 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 ARX-NITROFURANTOIN, or the medicine has passed its expiry date, ask your pharmacist what to do with any left over.

Product Description

What it looks like

ARX-NITROFURANTOIN is available as 50 mg and 100 mg capsules. These are supplied in Blister Pack of 3 X 10 Capsules (30 capsules) per carton.

The 50 mg capsules are Size '3' opaque yellow cap and opaque white body hard gelatin capsule, imprinted with "EM28" with 360 degree thin band, in black ink on cap filled with yellow powder.

Registration number:

AUST R 373271

The 100 mg capsules are Size '2' opaque yellow cap and opaque yellow body hard gelatin capsule, imprinted with "EM29" with 360 degree thin band, in black ink on cap filled with yellow powder.

Registration number:

AUST R 373270

Ingredients

ARX-NITROFURANTOIN capsules contain either 50 mg or 100 mg of nitrofurantoin (Macrocrystals) as the active ingredient. Other ingredients include Lactose Monohydrate, Pregelatinized Starch and purified talc.

The capsule shells contain gelatin, titanium dioxide, quinoline yellow, Iron oxide Yellow, sodium lauryl sulfate and Black Ink TEK SW 9008

Supplier

ARX-NITROFURANTOIN is supplied in Australia by:

Luminarie Pty Ltd

Distributed by:

Arrotex Pharmaceuticals

15–17 Chapel Street

Cremorne VIC 3121

This leaflet was prepared in November 2022.