

ARX-NITROFURANTOIN

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARX-NITROFURANTOIN?

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

For more information, see Section [1. Why am I using ARX-NITROFURANTOIN?](#) in the full CMI.

2. What should I know before I use ARX-NITROFURANTOIN?

Do not use if you have ever had an allergic reaction to nitrofurantoin or any of the ingredients listed at the end of the CMI. Do not take ARX-Nitrofurantoin if you are close to giving birth or have severe kidney problems. Do not give ARX-Nitrofurantoin to infants under three (3) months of age.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ARX-NITROFURANTOIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-NITROFURANTOIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ARX-NITROFURANTOIN?

- Follow directions given to you by your doctor and other health professionals carefully.

More instructions can be found in Section [4. How do I use ARX-NITROFURANTOIN?](#) in the full CMI.

5. What should I know while using ARX-NITROFURANTOIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ARX-NITROFURANTOIN. • If you have to have any urine or blood tests, tell your doctor you are taking ARX-NITROFURANTOIN. • If the symptoms of your infection do not improve, or if they become worse, tell your doctor
Things you should not do	• Do not stop using this medicine suddenly.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ARX-NITROFURANTOIN affects you. ARX-NITROFURANTOIN may cause dizziness or drowsiness in some people.
Looking after your medicine	• Store below 25°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

The more common side effects are nausea, vomiting and flatulence.

Some of the more serious side effects are allergic reactions, numbness or tingling in any area of the body, liver problems (with symptoms such as yellowing of the skin and eyes, lower back pain, dark urine, tiredness and a general feeling of being unwell), breathing issues and fever, chills, cough, or chest pain, asthma attacks, and diarrhoea (which may occur up to several weeks after taking ARX-Nitrofurantoin).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARX-NITROFURANTOIN CAPSULES

Active ingredient(s): *nitrofurantoin (macrocrystals)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-Nitrofurantoin Capsules. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARX-NITROFURANTOIN.**

Where to find information in this leaflet:

- [1. Why am I using ARX-NITROFURANTOIN?](#)
- [2. What should I know before I use ARX-NITROFURANTOIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARX-NITROFURANTOIN?](#)
- [5. What should I know while using ARX-NITROFURANTOIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ARX-NITROFURANTOIN?

ARX-NITROFURANTOIN contains the active ingredient nitrofurantoin. 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.

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

2. What should I know before I use ARX-NITROFURANTOIN?

Warnings

Do not use ARX-NITROFURANTOIN if:

- you are allergic to nitrofurantoin, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have severe kidney problems
- you are pregnant or close to giving birth as there is a risk that it might affect the baby.

Infants under three (3) months of age should not be given ARX-NITROFURANTOIN.

Check with your doctor if you:

- have any other medical conditions
- have kidney problems

- have anaemia (a blood disorder), diabetes, or vitamin B deficiency
- 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.
- Have lung disease
- Have liver or kidney disease
- take any medicines for any other condition

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with ARX-NITROFURANTOIN.

These medicines may be affected by ARX-NITROFURANTOIN or may affect how well they work.

- 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

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARX-NITROFURANTOIN.

4. How do I use ARX-NITROFURANTOIN?

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.

How much to take

Adults

- If you already have an infection: The usual dose is one (1) capsule (either 50 mg or 100 mg strength) four times daily.
- To prevent an infection: The usual dose is one (1) capsule (either 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.

Follow the instructions provided and use ARX-NITROFURANTOIN until your doctor tells you to stop.

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

When to take ARX-NITROFURANTOIN

- 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.

If you forget to use ARX-NITROFURANTOIN

ARX-NITROFURANTOIN should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, then go back to taking your medicine as you would normally.

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

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

If you use too much ARX-NITROFURANTOIN

If you think that you have used too much ARX-NITROFURANTOIN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ARX-NITROFURANTOIN?

Things you should 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.

Remind any doctor, dentist or pharmacist you visit that you are using ARX-NITROFURANTOIN.

Things you should not do

- Do not stop taking your medicine before you finish the 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-NITROFURANTOIN affects you.

ARX-NITROFURANTOIN may cause dizziness or drowsiness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may [insert effect relevant to use of the medicine].

Looking after your medicine

- 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.
- ARX-NITROFURANTOIN must be stored where it stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• nausea and vomiting • flatulence (passing wind) • diarrhoea • headache and dizziness • drowsiness and altered mood • feeling weak	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• 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.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ARX-NITROFURANTOIN contains

Active ingredient (main ingredient)	nitrofurantoin
Other ingredients (inactive ingredients)	• Lactose monohydrate • Pregelatinized maize starch • Purified talc Capsule shells contain: • Gelatin • Titanium dioxide • Quinoline yellow • Iron oxide yellow • Sodium lauryl sulfate • Black ink TEK SW 9008
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

What ARX-NITROFURANTOIN 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. (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. (AUST R 373270).

Who distributes ARX-NITROFURANTOIN

Arrotex Pharmaceuticals Pty Ltd

15–17 Chapel Street

Cremorne VIC 3121

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