

ARX-NALTREXONE

Consumer Medicine Information (CMI) summary

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

1. Why am I taking ARX-NALTREXONE?

ARX-NALTREXONE contains the active ingredient Naltrexone hydrochloride. ARX-NALTREXONE is used to help opiate drug addicts kick the habit. It is also used to help alcoholics dry out and remain abstinent.

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

2. What should I know before I take ARX-NALTREXONE?

Do not take if you have ever had an allergic reaction to ARX-NALTREXONE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions.

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

3. What if I am taking other medicines?

Some medicines may interfere with ARX-NALTREXONE 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 take ARX-NALTREXONE?

- The usual dose is one tablet every day

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

5. What should I know while taking ARX-NALTREXONE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ARX-NALTREXONE.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine suddenly• Do not use any other medicines while using ARX-NALTREXONE unless you have discussed this with your doctor or pharmacist.
Driving or using machines	<ul style="list-style-type: none">• ARX-NALTREXONE may affect your ability to drive or operate machinery. Be careful before you drive or use any machines or tools until you know how ARX-NALTREXONE affects you
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol
Looking after your medicine	<ul style="list-style-type: none">• Store below 25° C• Do not freeze

For more information, see Section [5. What should I know while taking ARX NALTREXONE?](#) in the full CMI.

6. Are there any side effects?

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

If you have stomach pain lasting more than a few days, white bowel movements, dark urine, or yellowing of your eyes, you should stop taking ARX-NALTREXONE immediately and see your doctor as soon as possible.

If you have an allergic reaction or notice gastrointestinal bleeding (blood in your stool), call your doctor straight away, or go straight to the Emergency Department.

ARX-NALTREXONE

Active ingredient: *Naltrexone hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking ARX-NALTREXONE?

ARX-NALTREXONE contains the active ingredient **Naltrexone hydrochloride**. ARX-NALTREXONE is an opiate antagonist. This means it fights the effects of opiate drugs like heroin on the body, and blocks euphoria (or “high”) due to these opiates.

Your doctor may have prescribed ARX-NALTREXONE for another use. Ask your doctor if you have any questions about why ARX-NALTREXONE has been prescribed for you. ARX-NALTREXONE is not addictive.

ARX-NALTREXONE is used to help opiate drug addicts kick the habit. It is also used to help alcoholics dry out and remain abstinent.

2. What should I know before I take ARX-NALTREXONE?

Warnings

ARX-NALTREXONE is not suitable for everyone.

Do not take ARX-NALTREXONE if:

- you had an allergic reaction to ARX-NALTREXONE
- you are allergic to Naltrexone hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.

Some of the symptoms of an allergic reaction may include, but are not limited to:

- difficulty in breathing, wheezing
- swelling of the face or tongue

- an itchy skin rash

- **Do not take ARX-NALTREXONE if you are still using heroin or drugs like it.** If you take ARX-NALTREXONE right after taking an opiate you will suffer withdrawal symptoms (cold turkey) (such as nausea, vomiting, shakiness, sweating and anxiety) which may be severe. Your doctor may give you a test called a NARCAN challenge. This is to see if you are still using heroin or drugs like it. If this test result is positive for heroin use, you will not be prescribed ARX-NALTREXONE.
- **Do not take ARX-NALTREXONE if you have hepatitis or liver failure.** Hepatitis is liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.
- **Do not take ARX-NALTREXONE if you are on certain pain killers.** Ask your doctor or pharmacist.
- **Do not take ARX-NALTREXONE if you are experiencing withdrawal symptoms.**

Do not take ARX-NALTREXONE after the expiry date printed on the pack or if the packaging is torn or seems to have been opened, or the tablets do not look quite right, see [7. Product details](#).

Check with your doctor if you:

- Are taking thioridazine or disulfiram
- Have or had any liver disease
- Have or had any kidney disease
- Have allergies to
 - Any other medicines
 - Any other substances such as food, preservatives, or dyes
- Are under 18 years of age

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

Do not take ARX-NALTREXONE if you are pregnant or breast feeding unless your doctor tells you it is safe.

Check with your doctor if you intend to become pregnant 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. These

medicines may be affected by ARX-NALTREXONE or they may affect how well ARX-NALTREXONE works.

Tell your doctor if you are taking thioridazine or disulfiram.

ARX-NALTREXONE may reduce or stop the effect of some cough and cold medicines, some medicines that treat loose bowel motions and some pain killers. **If this happens, do not take larger doses of these other medicines. If you do, you may become very sick. Talk to your doctor. Your doctor will advise you.**

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-NALTREXONE.

4. How do I take ARX-NALTREXONE?

How much to take

- The usual dose is one tablet every day.
- You will usually take ARX-NALTREXONE for at least 3 months, but it may be much longer. The time depends on how quickly you recover from alcohol or heroin addiction. Your doctor will decide the dose that is most appropriate for you. Please follow your doctor's instructions about how and when to take ARX-NALTREXONE.
- You should not stop taking ARX-NALTREXONE, or reduce the dose without first talking to your doctor. Depending on your response and on any side effects that you may experience, your doctor may adjust your dose of ARX-NALTREXONE, upward or downward, or may temporarily discontinue your medicine
- Follow the instructions provided and use ARX-NALTREXONE until your doctor tells you to stop.

If you stop taking ARX-NALTREXONE and restart your heroin habit, you are at risk of being more sensitive to opiates. Therefore, restarting your heroin habit after stopping ARX-NALTREXONE can lead to death from opiate overdose. You should talk to your doctor before you stop taking ARX-NALTREXONE and before you start taking heroin again

If you forget to take ARX-NALTREXONE

ARX-NALTREXONE should be used regularly at the same time each day. If you miss your dose at the usual time, take your next dose at its regular time.

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

Call your doctor or pharmacist if you are not sure what to do.

If you take too much ARX-NALTREXONE

If you think that you have used too much ARX-NALTREXONE, 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 taking ARX-NALTREXONE?

Things you should do

Make sure that all of your doctors, dentists and pharmacists know about your use of ARX-NALTREXONE. Remind them if any new medicines are about to be started, or if you are about to have a medical or dental procedure.

Call your doctor straight away if you:

- become pregnant while taking ARX-NALTREXONE.

Things you should not do

- Do not use any other medicines while using ARX-NALTREXONE unless you have discussed this with your doctor or pharmacist. This includes medicines you can buy without a prescription from a pharmacy, supermarket or health food shop or street drugs.
- ARX-NALTREXONE may not protect you if you take large amounts of an opiate in an attempt to overcome the blocking effects of ARX-NALTREXONE. Large doses of opiate can lead to difficulty in breathing and even to death from opiate overdose.
- Do not use ARX-NALTREXONE to treat any complaint other than that directed by your doctor. It may not be safe to use ARX-NALTREXONE for another complaint.
- Do not stop taking ARX-NALTREXONE, or lower the dosage, without checking with your doctor.
- Do not stop taking ARX-NALTREXONE because you are feeling better unless advised to do so by your doctor.
- ARX-NALTREXONE should only be used by the person for whom it was prescribed. Do not give ARX-NALTREXONE to someone else even if the symptoms are the same. It may not be safe for another person to use ARX-NALTREXONE. It may harm them.
- **Do not give your tablets to people who are known to be dependent on opiate drugs because a withdrawal syndrome "cold turkey" may be precipitated. Signs and symptoms (such as nausea, vomiting, shakiness, sweating and anxiety) which may be severe may develop within five minutes. If this happens, call a doctor.**

Driving or using machines

ARX-NALTREXONE may affect your ability to drive or operate machinery. Be careful before you drive or use any machines or tools until you know how ARX-NALTREXONE affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol while you are taking ARX-NALTREXONE, your blood alcohol level increases in the same way just as it would if you are not taking ARX-NALTREXONE. As this level rises, you can become physically and mentally impaired. The use of ARX-NALTREXONE will not change this.

Looking after your medicine

- Store below 25° C
- Keep the tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.
- Do not freeze

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 window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking ARX-NALTREXONE or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over

Getting rid of any unwanted medicine

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

Do not take 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.

Other side effects not listed here may occur in some people. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ARX-NALTREXONE.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: <ul style="list-style-type: none"> • nausea, vomiting, diarrhoea, constipation, stomach pain or cramps 	Speak to your doctor if you have any of these less

Nervous system: <ul style="list-style-type: none"> • headache, dizziness, nervousness, drowsiness, feeling anxious or irritable, difficulty sleeping Respiratory: <ul style="list-style-type: none"> • chest pain Musculoskeletal: <ul style="list-style-type: none"> • joint and muscle pain Skin and subcutaneous tissue: <ul style="list-style-type: none"> • rash Reproductive system: <ul style="list-style-type: none"> • delayed ejaculation General: <ul style="list-style-type: none"> • tiredness, thirsty, loss of appetite, sweating, increased tears, feeling down, chills, increased energy. 	serious side effects and they worry you.
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Serious side effects

Serious side effects	What to do
General: <ul style="list-style-type: none"> • swelling to the face, lips, tongue or throat which may cause difficulty in swallowing or breathing; Respiratory: <ul style="list-style-type: none"> • Wheezing Skin and subcutaneous tissue <ul style="list-style-type: none"> • severe and sudden onset of pinkish, itchy swelling of the skin; Gastrointestinal: <ul style="list-style-type: none"> • gastrointestinal bleeding (blood in your stool) • If you have stomach pain lasting more than a few days, white bowel movements, dark urine, or yellowing of your eyes, you should stop taking ARX-NALTREXONE immediately and see your doctor as soon as possible. 	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.

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.

ARX-NALTREXONE is not addictive.

What ARX-NALTREXONE contains

Active ingredient (main ingredient)	Naltrexone hydrochloride
Other ingredients (inactive ingredients)	- crosopvidone - microcrystalline cellulose - colloidal anhydrous silica, - magnesium stearate - Opadry yellow YS-1-6378G
Potential allergens	lactose monohydrate

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

What ARX-NALTREXONE looks like

ARX-NALTREXONE tablets are yellow coloured, oval, biconvex, film coated tablets with break line on one side and plain on other side (Aust R 386568).

Where to go for further information

Your doctor is the best person to answer any further questions you may have about ARX-NALTREXONE.

Anything your doctor tells you about ARX-NALTREXONE should be followed even if it is different from what is in this leaflet.

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Who distributes ARX-NALTREXONE

Arrotex Pharmaceuticals Pty Ltd

10-17 Chapel Street

Cremorne VIC 3121

<http://arrotex.com.au/>

This leaflet was prepared in March 2024.