

ARX-Abiraterone

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-Abiraterone?

ARX-Abiraterone contains the active ingredient abiraterone acetate. ARX-Abiraterone is used to treat prostate cancer that has spread to other parts of the body. It reduces the levels of the sex hormone testosterone.

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

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

Do not use if you have ever had an allergic reaction to abiraterone acetate or any of the ingredients listed at the end of the CMI.

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-Abiraterone?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-Abiraterone 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-Abiraterone?

- Always take ARX-Abiraterone exactly as your doctor has told you. You must check with your doctor if you are not sure.
- The usual daily dose of ARX-Abiraterone is four 250 mg tablets or two 500 mg tablets taken as a single dose.

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

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARX-Abiraterone.• Tell your doctor if you have or have had any medical conditions, particularly problems with your liver, high blood pressure and heart problems.• Stop taking ARX-Abiraterone and see a doctor immediately if you notice signs of low blood potassium.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.• Do not use ARX-Abiraterone if you have moderate or severe liver disease.• Do not use ARX-Abiraterone if you are pregnant or breastfeeding
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ARX-Abiraterone affects you
Looking after your medicine	250 mg tablets: Store Below 25° C 500 mg tablets: Store below 30° C

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

6. Are there any side effects?

Serious side effects include chest pain, heartbeat disorders, heart failure, rapid heart rate, muscle pains, adrenal gland problems and anaphylactic reaction. The most common side effects of ARX-Abiraterone are diarrhoea, fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures.

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-Abiraterone

Active ingredient(s): abiraterone acetate

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-Abiraterone. **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-Abiraterone.**

Where to find information in this leaflet:

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

1. Why am I using ARX-Abiraterone?

ARX-Abiraterone contains the active ingredient **abiraterone acetate**. ARX-Abiraterone belongs to a class of drugs known as anti-androgens (anti-testosterone). Testosterone, a natural hormone, helps prostate cancer to grow and spread.

ARX-Abiraterone is used to treat prostate cancer that has spread to other parts of the body. It reduces the levels of the sex hormone testosterone.

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

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

ARX-Abiraterone is not addictive.

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

Warnings

Do not use ARX-Abiraterone if:

- if you are pregnant or maybe potentially pregnant
ARX-Abiraterone is not for use in women and children.
- if you have severe liver failure
ARX-Abiraterone should not be used in patients with severe liver failure. Ask your doctor if you have questions.
- you are allergic to abiraterone acetate, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- if the packaging is torn or shows signs of tampering.

- if the expiry date (month and year) printed on the pack has passed.
- if you have moderate or severe liver disease. Your doctor will decide whether ARX-Abiraterone can be used if you have a mild liver problem.

Check with your doctor if you:

- have or have
- had any medical conditions, especially the following:
 - Problems with your liver
 - high blood pressure or
 - heart failure or
 - low blood potassium.

Taking ARX-Abiraterone can make these conditions worse. Taking prednisolone with ARX-Abiraterone helps to avoid worsening of these conditions. If you have these conditions, or other heart or blood vessel problems, discuss them with 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.

ARX-Abiraterone must not be taken by women who are pregnant or might be pregnant since ARX-Abiraterone may affect the baby.

If you are having sex with a pregnant woman you need to use a condom. If you are having sex with a woman who can become pregnant you need to use a condom and another effective birth control method.

If you are pregnant or might be pregnant, wear gloves if you need to touch or handle ARX-Abiraterone.

Check with your doctor if you are breastfeeding or intend to start breastfeeding.

ARX-Abiraterone must not be taken by women who breastfeeding since ARX-Abiraterone may affect the baby.

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-Abiraterone and affect how it works.

This may result in greater or lesser effects or even side effects from these medicines/treatments.

Your doctor will prescribe prednisolone to reduce the chance of high blood pressure, heart effects or low blood potassium. You will need to take prednisolone daily while you are taking ARX-Abiraterone. Do not stop taking prednisolone unless your doctor tells you to do this. During a medical emergency the dose of prednisolone may need to be increased. Your doctor will decide if this is necessary.

Your doctor may prescribe other treatments to be continued while you are taking ARX-Abiraterone and prednisolone.

If you have diabetes, your blood sugar may drop if you take ARX-Abiraterone plus prednisolone with some medicines for diabetes such as pioglitazone or repaglinide. Tell your doctor if you notice a drop in your blood sugar.

4. How do I use ARX-Abiraterone?

How much to take

- Always take ARX-Abiraterone exactly as your doctor has told you. You must check with your doctor if you are not sure.
- The usual daily dose of ARX-Abiraterone is four 250 mg tablets or two 500 mg tablets taken as a single dose.

When to take:

- Take as a single dose once daily on an empty stomach. ARX-Abiraterone must be taken at least one hour before or two hours after eating food
- Do not take ARX-Abiraterone with food.
- Taking ARX-Abiraterone with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.
- ARX-Abiraterone tablets should be swallowed whole with water. Do not break the tablets.
- ARX-Abiraterone is prescribed with prednisolone. The usual dose of prednisolone is 5 or 10 mg daily taken according to your doctor's instructions.
- You may also be required to take, or continue taking, additional hormone therapy. Follow all the instructions provided by your doctor. Ask your doctor or pharmacist if you have any questions.

If you forget to use ARX-Abiraterone

ARX-Abiraterone should be used regularly at the same time each day.

If you miss a daily dose of ARX-Abiraterone or prednisolone, take your normal dose the following day. If more than one daily dose is missed, talk to your doctor.

If you use too much ARX-Abiraterone

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

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using ARX-Abiraterone. If you are undergoing anaesthesia, tell your anaesthetist that you are taking ARX-Abiraterone

Do not stop taking ARX-Abiraterone unless your doctor tells you to do so.

Be sure to keep all your doctor's appointments so your progress can be checked.

Call your doctor straight away if you:

Notice any of these signs of low blood potassium:

- muscle weakness
- muscle twitches
- heart palpitations

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking ARX-Abiraterone.

If you have any further questions on the use of this product, ask your doctor.

Driving or using machines

Be careful driving or operating machinery until you know how ARX-Abiraterone affects you.

Looking after your medicine

Follow the instructions 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

250 mg tablet: Store below 25° C

500 mg tablet: Store below 30° C

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
<ul style="list-style-type: none">• diarrhoea• indigestion• fluid in legs and feet• urinary tract infection• an itchy rash (urticaria)• bone fractures.	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
Cardiovascular Symptoms: <ul style="list-style-type: none">• High blood pressure• Heart palpitations• Chest pain• Alternating fast and slow heart rate• Rapid heart rate• Heart failure Muscular Symptoms: <ul style="list-style-type: none">• Muscle weakness• Muscle twitches• Muscle pains Respiratory Symptoms: <ul style="list-style-type: none">• Shortness of breath• Difficulty swallowing or breathing General Symptoms: <ul style="list-style-type: none">• Fatigue or weakness• Feeling dizzy• Feeling faint Urinary Symptoms: <ul style="list-style-type: none">• Blood in urine Allergic Reactions: <ul style="list-style-type: none">• Swollen face, lips, tongue, or throat	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-Abiraterone contains

Active ingredient (main ingredient)	abiraterone acetate
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose croscarmellose sodium sodium lauryl sulfate magnesium stearate hypromellose colloidal silicon dioxide. Opadry II Purple 85F500067
Potential allergens	Lactose

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

What ARX-Abiraterone looks like

ARX-Abiraterone 250 mg tablet is white to off white, oval shaped, film coated tablets, debossed with "35" on one side and plain on other side. (AUST R 490407).

ARX-Abiraterone 500 mg tablet is Pinkish brown color, oval shaped, biconvex, film coated tablets, debossed with "46" on one side and plain other side (AUST R 490408).

Who distributes ARX-Abiraterone

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

Australia

www.arrotex.com.au

This leaflet was prepared in August 2025.