

ARABITRO

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 ARABITRO?

ARABITRO contains the active ingredient abiraterone acetate. ARABITRO 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 ARABITRO?](#) in the full CMI.

2. What should I know before I use ARABITRO?

Do not use if you have ever had an allergic reaction to ARABITRO 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 ARABITRO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARABITRO 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 ARABITRO?

- Always take ARABITRO exactly as your doctor has told you. You must check with your doctor if you are not sure.
- The usual daily dose of ARABITRO is four 250 mg tablets or two 500 mg tablets taken as a single dose.
- ARABITRO must be taken on an empty stomach, at least one hour before or at least two hours after food.

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

5. WHAT SHOULD I KNOW WHILE USING ARABITRO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARABITRO.• If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking ARABITRO.• If you are undergoing anaesthesia, tell your anaesthetist that you are taking ARABITRO.• Be sure to keep all your doctor's appointments so your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine unless your doctor tells you to do so.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ARABITRO affects you.• It is thought that ARABITRO will not affect your ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Keep in original container to protect them from moisture.

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

6. Are there any side effects?

The most common side effects of ARABITRO are diarrhoea, fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures.

Serious side effects: blood in urine, chest pain, heart beat disorders, heart failure, rapid heart rate, muscle pains and adrenal gland problems.

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.

ARABITRO

Active ingredient(s): *abiraterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARABITRO. **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 ARABITRO.**

Where to find information in this leaflet:

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

1. Why am I using ARABITRO?

ARABITRO contains the active ingredient **abiraterone acetate**. ARABITRO belongs to class of drugs known as anti-androgens.

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

2. What should I know before I use ARABITRO?

Warnings

Do not use ARABITRO if:

- you are allergic (hypersensitive) 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.
- the packaging is torn or shows signs of tampering.
- the expiry date (month and year) printed on the pack has passed. If you take ARABITRO after the expiry date it may not work.
- you are pregnant or maybe potentially pregnant. ARABITRO is not for use in women and children.
- you have severe liver failure. ARABITRO should not be used in patients with severe liver failure. Ask your doctor if you have questions.
- you are being treated with XOFIGO.
- ARABITRO and XOFIGO, a radiation therapy, should not be used together.

Check with your doctor if you:

- have any other medical conditions
- problems with your liver.

You should not take ARABITRO if you have moderate or severe liver disease. Your doctor will decide whether ARABITRO can be used if you have mild liver problem.

- high blood pressure and heart problems

ARABITRO can make high blood pressure or heart failure or low blood potassium worse. If you have these conditions, or other heart or blood vessel problems, discuss them with your doctor.

- take any medicines for any other condition

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

ARABITRO must not be taken by women who are pregnant or breast-feeding or might be pregnant since ARABITRO 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 ARABITRO.

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.

To reduce the chance of developing high blood pressure or heart effects or low blood potassium, your doctor will prescribe either prednisone or prednisolone. You need to take one of these drugs daily while you are taking ARABITRO. Do not stop taking prednisone or prednisolone unless your doctor tells you to do this. During a medical emergency the dose of prednisone or prednisolone may need to be increased. Your doctor will look at your situation and tell you whether this is necessary.

Some medicines may interfere with ARABITRO and affect how it works.

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

Your doctor may prescribe other treatments to be continued while you are taking ARABITRO and prednisone or prednisolone.

If you have diabetes, your blood sugar may drop if you take ARABITRO plus prednisone/prednisolone with some medicines for diabetes such as pioglitazone or repaglinide.

Tell your doctor if you monitor your blood sugar while taking a medicine for diabetes and notice a drop in your blood sugar.

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

4. How do I take ARABITRO?

How much to take

- The usual daily dose of ARABITRO is four 250 mg tablets or two 500 mg tablets taken as a single dose.
- Follow the instructions provided and use ARABITRO until your doctor tells you to stop.

When to take ARABITRO

Take ARABITRO at about the same time each day.

How to take ARABITRO

- ARABITRO must be taken as a single dose once daily on an empty stomach. ARABITRO must be taken at least two hours after eating and food must not be eaten for at least one hour after taking ARABITRO.
- Taking ARABITRO with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.
- ARABITRO tablets should be swallowed whole with water. Do not break the tablets.
- ARABITRO is prescribed with prednisone or prednisolone. The usual dose of prednisone or 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 instructions provided by your doctor. Ask your doctor or pharmacist if you have any questions.

If you forget to take ARABITRO

ARABITRO should be used regularly at the same time each day.

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

If you take too much ARABITRO

If you think that you have used too much ARABITRO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia 13 11 26 New Zealand 0800 764 766), 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 ARABITRO?

Things you should do:

Do not stop taking ARABITRO unless your doctor tells you to do so.

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

Your doctor will want to do some blood and other tests from time to time to check on your progress.

Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.

Ask your doctor or pharmacist if you have any questions.

Tell any other doctors and pharmacists who are treating you that you are taking ARABITRO. If you are undergoing anaesthesia, tell your anaesthetist that you are taking ARABITRO.

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

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

Things to be careful of

Driving and using machines

Be careful before you drive or use any machines or tools until you know how ARABITRO affects you.

It is thought that ARABITRO will not affect your ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep ARABITRO tablets in a location where the temperature stays below 25°C.
- Keep your tablets in the original container to protect them from moisture.

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.

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. Stop taking ARABITRO and see a doctor immediately if you notice signs of low blood potassium:

– muscle weakness, muscle twitches, heart palpitations.

The most common side effects of ARABITRO are diarrhoea, fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• diarrhoea,• fluid in legs and feet,• urinary tract infection,• high blood pressure• 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
<ul style="list-style-type: none">• signs of low blood potassium levels such as muscle weakness, muscle twitches, heart palpitations.• high fat levels in your blood• liver function test increases• blood in urine• chest pain• heart beat disorders• heart failure• rapid heart rate• muscle pains• bone fractures• adrenal gland problems• anaphylactic reaction (severe allergic reactions that include, but are not limited to difficulty swallowing or breathing, swollen face, lips, tongue or throat, or an itchy rash (urticaria))	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 above may also 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, or in NZ to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. 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

What ARABITRO contains

Active ingredient (main ingredient)	Abiraterone acetate
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose croscarmellose sodium povidone sodium lauryl sulfate magnesium stearate silica amorphous. The tablet coating of the 500 mg tablet contains: iron oxide black iron oxide red macrogol 4000 polyvinyl alcohol talc titanium dioxide.
Potential allergens	lactose monohydrate

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

Storage

ARABITRO 250 and 500 mg tablets:

Store below 25°C. Keep in original container to protect from moisture.

What ARABITRO looks like

ARABITRO 250 mg uncoated tablets are white to off-white, oval-shaped uncoated tablets, debossed with “G” on one side and “135” on other side.

ARABITRO 500 mg film-coated tablets are brownish pink, oval-shaped, film-coated tablets, debossed with “G” on one side and “121” on the other side.

Who distributes ARABITRO

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