

ABIRATERONE VIATRIS

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 ABIRATERONE VIATRIS?

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

2. What should I know before I use ABIRATERONE VIATRIS?

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

3. What if I am taking other medicines?

Some medicines may interfere with ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS?

- Always take ABIRATERONE VIATRIS exactly as your doctor has told you. You must check with your doctor if you are not sure.
- The usual daily dose of ABIRATERONE VIATRIS is four 250 mg tablets or two 500 mg tablets taken as a single dose.
- ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS?](#) in the full CMI.

5. What should I know while using ABIRATERONE VIATRIS?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ABIRATERONE VIATRIS.• If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking ABIRATERONE VIATRIS.• If you are undergoing anaesthesia, tell your anaesthetist that you are taking ABIRATERONE VIATRIS.• 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 ABIRATERONE VIATRIS affects you.• It is thought that ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of ABIRATERONE VIATRIS 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.

ABIRATERONE VIATRIS

Active ingredient(s): *abiraterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ABIRATERONE VIATRIS. **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 ABIRATERONE VIATRIS.**

Where to find information in this leaflet:

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

1. Why am I using ABIRATERONE VIATRIS?

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

ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS?

Warnings

Do not use ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS after the expiry date it may not work.
- you are pregnant or maybe potentially pregnant.
ABIRATERONE VIATRIS is not for use in women and children.
- you have severe liver failure.
ABIRATERONE VIATRIS should not be used in patients with severe liver failure. Ask your doctor if you have questions.
- you are being treated with XOFIGO.
ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS if you have moderate or severe liver disease. Your doctor will decide whether ABIRATERONE VIATRIS can be used if you have mild liver problem.
- high blood pressure and heart problems.
ABIRATERONE VIATRIS 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

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

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 ABIRATERONE VIATRIS. 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 ABIRATERONE VIATRIS and affect how it works. These include:

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 ABIRATERONE VIATRIS and prednisone or prednisolone.

If you have diabetes, your blood sugar may drop if you take ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS.

4. How do I use ABIRATERONE VIATRIS?

How much to take

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

When to take ABIRATERONE VIATRIS

- Take ABIRATERONE VIATRIS at about the same time each day.

How to take ABIRATERONE VIATRIS

- ABIRATERONE VIATRIS must be taken as a single dose once daily on an empty stomach. ABIRATERONE VIATRIS must be taken at least two hours after eating and food must not be eaten for at least one hour after taking ABIRATERONE VIATRIS.
- Taking ABIRATERONE VIATRIS with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.
- ABIRATERONE VIATRIS tablets should be swallowed whole with water. Do not break the tablets.
- ABIRATERONE VIATRIS 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 use ABIRATERONE VIATRIS

ABIRATERONE VIATRIS should be used regularly at the same time each day.

If you miss a daily dose of ABIRATERONE VIATRIS 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 use too much ABIRATERONE VIATRIS

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 ABIRATERONE VIATRIS?

Things you should do

Do not stop taking ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS. If you are undergoing anaesthesia, tell your anaesthetist that you are taking ABIRATERONE VIATRIS.

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

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

Driving or using machines

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS 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 ABIRATERONE VIATRIS 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.

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 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 ABIRATERONE VIATRIS contains

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

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

What ABIRATERONE VIATRIS looks like

ABIRATERONE VIATRIS 250 mg uncoated tablets are white to off-white, oval-shaped uncoated tablets, debossed with "G" on one side and "135" on other side (AUST R 453789).

ABIRATERONE VIATRIS 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 (AUST R 453790).

Who distributes ABIRATERONE VIATRIS

Sponsor

Glenmark Pharmaceuticals Australia Pty Ltd
Suite 1503, Level 15 14 Martin Place
Sydney, NSW 2000

Australia

Distributor

ABIRATERONE VIATRIS is distributed in Australia by:
Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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