

ABIRATERONE-TEVA

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-TEVA?

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

2. What should I know before I use ABIRATERONE-TEVA?

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

3. What if I am taking other medicines?

Some medicines may interfere with ABIRATERONE-TEVA 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-TEVA?

- Follow all directions given to you by your doctor or pharmacist carefully.
- **DO NOT TAKE ABIRATERONE-TEVA WITH FOOD.** ABIRATERONE-TEVA must be taken at least two hours after eating and food must not be eaten for at least one hour after taking ABIRATERONE-TEVA.

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

5. What should I know while using ABIRATERONE-TEVA?

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are using ABIRATERONE-TEVA. ● If you are undergoing anaesthesia, tell your anaesthetist that you are taking ABIRATERONE-TEVA. ● If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking ABIRATERONE-TEVA. ● Keep all of your doctor's appointments so that your progress can be checked.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine unless your doctor tells you to do so.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● It is thought that ABIRATERONE-TEVA 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 bottle tightly closed in order to protect from moisture.

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

6. Are there any side effects?

The most common side effects of ABIRATERONE-TEVA are diarrhoea, fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures. Less common side effects are high blood fat levels, liver function test increases, indigestion, blood in urine, chest pain, heart beat disorders, heart failure, rapid heart rate, muscle pains, adrenal gland problems and anaphylactic reaction. 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-TEVA

Active ingredient: *abiraterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ABIRATERONE-TEVA. **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-TEVA.**

Where to find information in this leaflet:

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

1. Why am I using ABIRATERONE-TEVA?

ABIRATERONE-TEVA contains the active ingredient abiraterone acetate.

ABIRATERONE-TEVA is used to treat prostate cancer that has spread to other parts of the body. It reduces the levels of the sex hormone testosterone. ABIRATERONE-TEVA is not addictive.

2. What should I know before I use ABIRATERONE-TEVA?

Warnings

Do not use ABIRATERONE-TEVA if:

- you are allergic to **abiraterone acetate**, or any of the ingredients listed at the end of this leaflet.
- if you are pregnant or maybe potentially pregnant.
- if you have severe liver failure.
- if you are being treated with XOFIGO.

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

ABIRATERONE-TEVA may affect your liver. When you are taking ABIRATERONE-TEVA your doctor will check your blood to look for any effects of ABIRATERONE-TEVA on your liver.

Check with your doctor if you:

- have any other medical conditions or problems with your liver, high blood pressure and heart problems, or are pregnant
- take any medicines for any other condition

ABIRATERONE-TEVA can make high blood pressure or heart failure or low blood potassium worse. Taking prednisolone with ABIRATERONE-TEVA 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed since ABIRATERONE-TEVA 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-TEVA.

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 ABIRATERONE-TEVA and affect how it works.

This may result in greater or lesser effects or even side effects from these medicines. Tell your doctor if you are taking any other medicines or receiving other treatments, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop. Your doctor can tell you whether you can continue the medicines/treatments you are taking or reduce the dose.

If you have diabetes, your blood sugar may drop if you take ABIRATERONE-TEVA plus 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.

To reduce the chance of developing high blood pressure or heart effects or low blood potassium, your doctor will prescribe prednisolone. You need to take prednisolone daily while you are taking ABIRATERONE-TEVA. Do not stop taking prednisolone unless your doctor tells you to do this.

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

During a medical emergency the dose of prednisolone may need to be increased. Your doctor will look at your situation and tell you whether this is necessary.

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-TEVA.

4. How do I use ABIRATERONE-TEVA?

How much to take

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

When to take ABIRATERONE-TEVA

- ABIRATERONE-TEVA should be used as a single dose once daily on an empty stomach. ABIRATERONE-TEVA must be taken at least two hours after eating and food must not be eaten for at least one hour after taking ABIRATERONE-TEVA. Taking ABIRATERONE-TEVA with food causes more

of this medicine to be absorbed by the body than is needed and this may cause side effects.

- ABIRATERONE-TEVA tablets should be swallowed whole with water. Do not break the tablets.
- ABIRATERONE-TEVA 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 instructions provided by your doctor. Ask your doctor or pharmacist if you have any questions.

If you forget to use ABIRATERONE-TEVA

ABIRATERONE-TEVA should be used regularly at the same time each day. If you miss a daily dose of ABIRATERONE-TEVA 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-TEVA

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

You should immediately:

- phone the Poisons Information Centre (In Australia by calling **13 11 26** and in New Zealand **0800 POISON [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 ABIRATERONE-TEVA?

Things you should do

Do not stop taking ABIRATERONE-TEVA unless your doctor tells you to do so.

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

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

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.

Remind any doctor, dentist or pharmacist you visit that you are using ABIRATERONE-TEVA.

If you are undergoing anaesthesia, tell your anaesthetist that you are taking ABIRATERONE-TEVA.

Things you should not do

- Do not stop using this medicine unless your doctor tells you to do so.

Driving or using machines

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

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- ABIRATERONE-TEVA tablets should be kept out of reach of children, in a location where the temperature stays below 25°C

Store in original container 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. 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.

Side effects

Side effects	What to do
Diarrhoea, fluid in legs and feet, high fat levels in your blood, liver function test increases, indigestion, muscle pains, adrenal gland problems	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects

Serious side effects	What to do
Signs of low blood potassium: <ul style="list-style-type: none">• muscle weakness, muscle twitches, heart palpitations.	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.

Serious side effects	What to do
Urinary tract infection, high blood pressure, bone fractures, blood in urine, chest pain, heart beat disorders, heart failure, rapid heart rate, 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))	

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 OR Medsafe online at www.tga.gov.au/reporting-problems OR <https://nzphvc.otago.ac.nz/reporting/>. 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-TEVA contains

Active ingredient (main ingredient)	Abiraterone acetate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● lactose monohydrate● microcrystalline cellulose● croscarmellose sodium● povidone● sodium lauryl sulfate● magnesium stearate● colloidal silicon dioxide● Opadry II complete film coating system 85F18378 White

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

What ABIRATERONE-TEVA looks like

ABIRATERONE-TEVA 250 mg film coated tablets are white to off-white, oval-shaped tablets, debossed with Teva on one side and "1125" on the other side (AUST R 393322).

Who distributes ABIRATERONE-TEVA

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Teva Pharma (New Zealand) Ltd

Auckland, New Zealand

This leaflet was prepared in September 2023.