

# Abiraterone Sandoz®

## 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 taking Abiraterone Sandoz?

Abiraterone Sandoz contains the active ingredient abiraterone acetate. Abiraterone Sandoz is used to treat prostate cancer that has spread to other parts of the body.

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

### 2. What should I know before I use Abiraterone Sandoz?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Abiraterone Sandoz 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 Abiraterone Sandoz?

- The usual daily dose is four 250 mg tablets, two 500 mg tablets or one 1000 mg tablet taken as a single dose.
- Abiraterone Sandoz must be taken on an empty stomach, at least one hour before or at least two hours after food.
- Swallow the tablet whole with a glass of water and take at about the same time each day.

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

### 5. What should I know while taking Abiraterone Sandoz?

|                                    |   |
|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Abiraterone Sandoz.</li><li>• Be sure to keep all your doctor's appointments so your progress can be checked.</li><li>• Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.</li><li>• If you are undergoing anaesthesia, tell your anaesthetist that you are taking Abiraterone Sandoz.</li></ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>• Do not stop using this medicine unless your doctor tells you to do so.</li></ul>  |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Abiraterone Sandoz affects you.</li><li>• It is thought that Abiraterone Sandoz will not affect your ability to drive and use machines.</li></ul>   |
| <b>Drinking alcohol</b>            | <ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>  |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>• Keep Abiraterone Sandoz tablets in a location where the temperature stays below 25°C.</li><li>• Keep your tablets in the original container to protect them from moisture.</li></ul>  |

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

### 6. Are there any side effects?

Common side effects: 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 Sandoz®

Active ingredient(s): *abiraterone acetate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking Abiraterone Sandoz. **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 Sandoz.**

Where to find information in this leaflet:

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

## 1. Why am I taking Abiraterone Sandoz?

**Abiraterone Sandoz contains the active ingredient abiraterone acetate.** Abiraterone Sandoz is an androgen biosynthesis inhibitor which acts primarily to reduce the levels of the sex hormone testosterone.

**Abiraterone Sandoz is used to treat prostate cancer that has spread to other parts of the body.**

## 2. What should I know before I take Abiraterone Sandoz?

### Warnings

**Do not take Abiraterone Sandoz if:**

- you are allergic to abiraterone, 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 as passed. If you take Abiraterone Sandoz after the expiry date it may not work.
- If you are pregnant or maybe potentially pregnant. Abiraterone Sandoz is not for use in women and children.
- If you have severe liver failure. Abiraterone Sandoz should not be used with patients with severe liver failure.
- If you are being treated with Xofigo. Abiraterone Sandoz 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 Sandoz if you have moderate or severe liver disease. Your doctor will decide whether Abiraterone Sandoz can be used if you have mild liver problem.
- high blood pressure and heart problems
- 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

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.

Abiraterone Sandoz must not be taken by women who are pregnant or breastfeeding or might be pregnant since Abiraterone Sandoz 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 Sandoz.

## 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 prednisolone. You need to take one of these drugs daily while you are taking Abiraterone Sandoz. 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 look at your situation and tell you whether this is necessary.
- Your doctor may prescribe other treatments to be continued while you are taking Abiraterone Sandoz and prednisolone.

**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 Sandoz.**

## 4. How do I take Abiraterone Sandoz?

### How much to take

- The usual daily dose of Abiraterone Sandoz is four 250 mg tablets, two 500 mg tablets or one 1000 mg tablet taken as a single dose.
- Follow the instructions provided and use Abiraterone Sandoz until your doctor tells you to stop.

### When to take Abiraterone Sandoz

- Take Abiraterone Sandoz at about the same time each day.

### How to take Abiraterone Sandoz

- **DO NOT TAKE ABIRATERONE SANDOZ WITH FOOD.**
- Abiraterone Sandoz must be taken as a single dose once daily on an empty stomach. Abiraterone Sandoz must be taken at least two hours after eating and food must not be eaten for at least one hour after taking Abiraterone Sandoz.
- Taking Abiraterone Sandoz with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.
- Abiraterone Sandoz should be swallowed whole with water.
- If splitting the 1000 mg tablet is necessary to facilitate swallowing, break the tablet using a dedicated pill cutter at the time of administration. Swallow both halves of the tablet consecutively, one immediately after the other, without chewing. The split tablet should not be stored.
- Abiraterone Sandoz 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.

### If you forget to take Abiraterone Sandoz

Abiraterone Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, take your normal dose the following day.

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

If more than one daily dose is missed, talk to your doctor.

### If you use too much Abiraterone Sandoz

If you think that you have used too much Abiraterone Sandoz, 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 Abiraterone Sandoz?

### Things you should do

- 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.
- Tell any other doctors and pharmacists who are treating you that you are taking Abiraterone Sandoz.
- If you are undergoing anaesthesia, tell your anaesthetist that you are taking Abiraterone Sandoz.
- If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking Abiraterone Sandoz.
- If you have any further questions on the use of this product, ask your doctor.

### Things you should not do

- Do not stop taking 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 Sandoz affects you.**

It is thought that Abiraterone Sandoz 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 Sandoz 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.

### Less serious side effects

| Less serious side effects  | What to do   |
|--|--|
| <ul style="list-style-type: none"><li>• Diarrhoea</li><li>• Fluid in the legs and feet</li><li>• Urinary tract infection</li><li>• High blood pressure</li><li>• Indigestion</li></ul> | <b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b> |

### Serious side effects

| Serious side effects   | What to do  |
|--|---|
| <ul style="list-style-type: none"><li>• Signs of low blood potassium levels, such as muscle weakness, muscle twitches and heart palpitations.</li><li>• High fat levels in your blood</li><li>• Liver function test increases</li><li>• Blood in urine</li><li>• Chest pain</li><li>• Heart beat disorders</li><li>• Heart failure</li><li>• Rapid heart rate</li><li>• Muscle pains</li><li>• Bone fractures</li><li>• Adrenal gland problems</li><li>• 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))</li></ul> | <b>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.</b> |

**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](http://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 Sandoz contains

|   |  |
|---|--|
| <b>Active ingredient (main ingredient)</b>      | Each film-coated tablet contains 250 mg, 500 mg or 1000 mg of abiraterone acetate.   |
| <b>Other ingredients (inactive ingredients)</b> | <ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• microcrystalline cellulose</li><li>• croscarmellose sodium</li><li>• povidone</li><li>• sodium lauryl sulfate</li><li>• magnesium stearate</li><li>• colloidal silicon dioxide</li><li>• macrogol 3350</li><li>• polyvinyl alcohol</li><li>• talc</li><li>• titanium dioxide</li><li>• iron oxide red (500 mg only)</li><li>• iron oxide black (500 mg only)</li></ul> |
| <b>Potential allergens</b>                      | <ul style="list-style-type: none"><li>• lactose monohydrate</li></ul>  |

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

### What Abiraterone Sandoz looks like

Abiraterone Sandoz 250 mg – white to off-white, oval-shaped film-coated tablets, debossed with “250” on one side.

Available in blister packs of 120 tablets (AUST R 344891). Available in bottles of 120 tablets (AUST R 350471).

Abiraterone Sandoz 500 mg – purple, oval-shaped, film-coated tablets, debossed with “500” on one side.

Available in blister packs of 60 tablets (AUST R 344890). Available in bottles of 60 tablets (AUST R 350470).

Abiraterone Sandoz 1000 mg – white to off-white, oval-shaped film-coated tablets, with a break line on one side and plain on the other side.

Available in blister packs of 28 and 30 tablets (AUST R 346331). Available in bottles of 28 and 30 tablets (AUST R 350472).

*Not all strengths and pack sizes are available in Australia.*

## **Who distributes Abiraterone Sandoz**

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

This leaflet was prepared in September 2024.

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