

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 ZYRON™?

ZYRON™ contains the active ingredient abiraterone acetate.

ZYRON™ 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 taking ZYRON™?](#) in the full CMI.

2. What should I know before I take ZYRON™?

Do not take ZYRON™ if you have ever had an allergic reaction to it or any of the ingredients listed at the end of the CMI.

Do not take ZYRON™ if you are pregnant or may be potentially pregnant.

Do not take ZYRON™ if you have moderate–severe liver failure or if you are being treated with XOFIGO (a radiation therapy).

Talk to your doctor if you have high blood pressure, heart problems or take any other medicines.

For more information, see Section [2. What should I know before I take ZYRON™?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZYRON™ 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 ZYRON™?

The usual dose of ZYRON™ is four 250 mg tablets or two 500 mg tablets.

Tablets must be taken as a single dose once daily and must be taken on an empty stomach.

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

5. What should I know while taking ZYRON™?

Things you should do	<ul style="list-style-type: none">Stop taking ZYRON™, and tell your doctor immediately, if you start to have muscle weakness, muscle twitches or heart palpitations.Tell any surgeon, doctor, dentist or pharmacist you visit that you are taking ZYRON™.
Things you should not do	<ul style="list-style-type: none">Do not stop taking ZYRON™ unless your doctor tells you to do so.You should not give ZYRON™ to anyone else, even if they have the same condition as you.You should not take ZYRON™ to treat any other complaints.
Driving or using machines	<ul style="list-style-type: none">It is thought that ZYRON™ will not affect your ability to drive and use machines.
Looking after your medicine	<ul style="list-style-type: none">Store below 25°C.

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

6. Are there any side effects?

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

Other side effects include: high fat levels in your blood, liver function test increases, indigestion, blood in urine, chest pain, heartbeat disorders, heart failure, rapid heart rate, muscle pains, adrenal gland problems and severe allergic reactions.

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.

ZYRON™

Active ingredient: *Abiraterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZYRON™. **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 ZYRON™.**

Where to find information in this leaflet:

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

1. Why am I taking ZYRON™?

ZYRON™ contains the active ingredient abiraterone acetate.

ZYRON™ 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 ZYRON™ has been prescribed for you.

This medicine is available only with a doctor's prescription. ZYRON™ is not addictive.

2. What should I know before I take ZYRON™?

Warnings

Do not take ZYRON™:

- if you are allergic (hypersensitive) to abiraterone or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- if you have severe liver failure.
- if you are being treated with XOFIGO, a radiation therapy.
- if you are pregnant or may be potentially pregnant.

Check with your doctor if you:

- have or have had any medical conditions, especially:
 - problems with your liver
 - high blood pressure
 - heart problems
 - low blood levels of potassium.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to watch for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take ZYRON™ if you are pregnant or intend to become pregnant.

ZYRON™ is not for use in women and children.

Problems with your liver

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

ZYRON™ may affect your liver. When you are taking ZYRON™ your doctor will check your blood to look for any effects on your liver

High blood pressure and heart problems

ZYRON™ can make high blood pressure or heart failure or low blood potassium worse. Taking prednisone or prednisolone with ZYRON™ helps to avoid worsening of these conditions.

If you have these conditions, or other heart or blood vessel problems, discuss them with your doctor.

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 prednisolone daily while you are taking ZYRON™. 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 ZYRON™ and prednisolone.

ZYRON™ might interact with other medicines or treatments. This may result in greater or lesser effects or even side effects from these medicines/treatments. 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 ZYRON™ plus prednisolone with some medicines for

diabetes such as pioglitazone or repaglinide. Tell your doctor if you monitor your blood sugar while taking 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 ZYRON™.

4. How do I take ZYRON™?

How much ZYRON™ to take

The usual daily dose is four 250 mg tablets or two 500 mg tablets taken as a single dose.

Always take ZYRON™ exactly as your doctor has told you. You must check with your doctor if you are not sure.

How to take ZYRON™

DO NOT TAKE ZYRON™ WITH FOOD.

ZYRON™ must be taken as a single dose once daily on an empty stomach. ZYRON™ must be taken at least two hours after eating and food must not be eaten for at least one hour after taking ZYRON™.

Taking ZYRON™ with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.

ZYRON™ tablets should be swallowed whole with water. Do not break the tablets.

ZYRON™ 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.

When to take ZYRON™

ZYRON™ should be used once a day, ideally at the same time.

If you forget to use ZYRON™

If you miss a daily dose of ZYRON™ or prednisolone, 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 ZYRON™

If you think you or anybody else has taken too much ZYRON™, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do or go to the Emergency Department at your nearest hospital.

You can contact the Poisons Information Centre by calling:

- Australia – 13 11 26
- New Zealand – 0800 POISON or 0800 764 766.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ZYRON™?

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.**

Ask your doctor or pharmacist if you have any questions.

- **Tell any other doctors and pharmacists who are treating you that you are taking ZYRON™.**
- **If you are undergoing anaesthesia, tell your anaesthetist that you are taking ZYRON™.**
- **If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking ZYRON™.**

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

Things you should not do

- Do not stop taking ZYRON™ unless your doctor tells you to do so.
- Do not give ZYRON™ to anyone else, even if they have the same condition as you.
- Do not take ZYRON™ to treat any other medical complaints.

Things to be careful of

Driving and using machines

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

Looking after your medicine

Follow the instructions on the packaging on how to store ZYRON™ properly. The tablets should be stored where the temperature stays below 25°C.

ZYRON™ should be stored 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 windowsills.

Store ZYRON™ where children cannot reach it.

When to discard ZYRON™

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
More common side effects: <ul style="list-style-type: none">• diarrhoea• fluid in legs and feet• low blood potassium• 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">• muscle weakness• muscle twitches• heart palpitations• high fat levels in your blood• liver function test increases• indigestion• blood in urine• chest pain• heartbeat disorders• heart failure• rapid heart rate• muscle pains• 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

ZYRON™ is only available with a doctor's prescription.

What ZYRON™ contains

Active ingredients (main ingredients)	Abiraterone acetate 250 mg or 500 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• silicified microcrystalline cellulose• croscarmellose sodium• sodium lauryl sulfate• magnesium stearate• hypromellose• colloidal anhydrous silica. <p>The tablet coating contains:</p> <ul style="list-style-type: none">• iron oxide black (500 mg tablet only)• iron oxide red (500 mg tablet only)• macrogol 3350• polyvinyl alcohol• talc• titanium dioxide.

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

What ZYRON™ looks like

250 mg tablets – white to off-white, oval-shaped film coated tablets, plain on both sides.

Available in a white plastic bottle containing 120 tablets.

AUST R 449613

500 mg tablets – purple, oval-shaped, film -coated tablets, with a non-functional score line on one side and plain on the other side.

Available in blister packs of 60 tablets.

AUST R 449614

Who distributes ZYRON™

Nova Pharmaceuticals Australasia Pty Ltd

Suite 305, 10 Norbrik Drive,

Bella Vista NSW 2153

Toll free 1800 002 171

www.novapharm.com.au

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