

ZYTIGA®

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 ZYTIGA?

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

2. What should I know before I take ZYTIGA?

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

3. What if I am taking other medicines?

Some medicines may interfere with ZYTIGA 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 ZYTIGA?

- Always take ZYTIGA exactly as your doctor has told you.
- The usual daily dose of ZYTIGA is four 250 mg tablets or two 500 mg tablets taken orally as a single dose.
- DO NOT TAKE ZYTIGA WITH FOOD.
- ZYTIGA 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.

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

5. What should I know while taking ZYTIGA?

| | |
|-----------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist |
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| | <p>you visit that you are taking ZYTIGA.</p> <ul style="list-style-type: none"> • If you are undergoing anaesthesia, tell your anaesthetist that you are taking ZYTIGA. • Tell your doctor if you have problems with your liver, high blood pressure or heart problems. |
| Things you should not do | <ul style="list-style-type: none"> • Do not take ZYTIGA if you have severe liver failure. • Do not take ZYTIGA if you are being treated with XOFIGO, a radiation therapy. |
| Looking after your medicine | <ul style="list-style-type: none"> • 250 mg tablet bottle: Store below 25°C. • 500 mg tablet blister pack: Store below 30°C. |

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

6. Are there any side effects?

The most common side effects of ZYTIGA include diarrhoea, fluid in legs and feet, urinary tract infection, high blood pressure and bone fractures. Serious side

effects that require immediate medical attention include serious allergic reaction and low blood potassium. 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.

ZYTIGA®

Active ingredient(s): *abiraterone acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ZYTIGA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ZYTIGA.**

Where to find information in this leaflet:

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

1. Why am I taking ZYTIGA?

ZYTIGA contains the active ingredient abiraterone acetate. ZYTIGA belongs to a group of medicines called androgen biosynthesis inhibitor.

ZYTIGA 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 take ZYTIGA?

Warnings

Do not take ZYTIGA if:

- you are allergic to abiraterone acetate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.
- you have severe liver failure. ZYTIGA should not be used in patients with severe liver failure.
- if you are being treated with XOFIGO. ZYTIGA and XOFIGO, a radiation therapy, should not be used together.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - **Problems with your liver**

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

- **High blood pressure and heart problems**

ZYTIGA can make high blood pressure, heart failure, low blood potassium and irregular heartbeats worse. Taking prednisone or prednisolone with ZYTIGA helps to avoid worsening of these conditions.

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

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

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

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.

Women, infants and children

- ZYTIGA is not for use in women and children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines or receiving other treatments, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

ZYTIGA might interact with other medicines or treatments. This may result in greater or lesser effects or even side effects from these medicines or treatments.

Your doctor can tell you whether you can continue the medicines or treatments you are taking or reduce the dose.

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

4. How do I take ZYTIGA?

How much to take

- **The usual daily dose of ZYTIGA is four 250 mg tablets or two 500 mg tablets taken orally as a single dose.**
- Always take ZYTIGA exactly as your doctor has told you. You must check with your doctor if you are not sure.

When to take ZYTIGA

- **DO NOT TAKE ZYTIGA WITH FOOD**
- **ZYTIGA must be taken orally as a single dose once daily on an empty stomach.**
- **ZYTIGA must be taken at least two hours after eating and food must not be eaten for at least one hour after taking ZYTIGA.**
- Taking ZYTIGA with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.

How to take ZYTIGA

- ZYTIGA tablets should be swallowed whole with water. Do not break the tablets.
- ZYTIGA 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 ZYTIGA

ZYTIGA should be taken at the same time each day.

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

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

If you take too much ZYTIGA

If you think that you have taken too much ZYTIGA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (in Australia telephone **13 11 26**. In New Zealand telephone **0800 POISON** or **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 taking ZYTIGA?

Things you should do

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

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 ZYTIGA.

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.

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

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

- muscle weakness, muscle twitches, heart palpitations

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.

If you are undergoing anaesthesia, tell your anaesthetist that you are taking ZYTIGA.

If you are about to be started on any new medicines, tell any doctor, dentist or pharmacist you visit that you are taking ZYTIGA.

Things you should not do

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

Monitoring blood pressure, potassium levels and fluid retention

- QT prolongation and Torsades de Pointes have been observed in patients who develop low blood potassium (hypokalemia) while taking ZYTIGA.
- Your blood pressure, serum potassium and signs and symptoms of fluid retention will be monitored clinically at least monthly.

Monitoring liver function

- ZYTIGA may affect your liver. Rarely, failure of the liver to function (called acute liver failure) may occur, which can lead to death.
- When you are taking ZYTIGA your doctor will check your blood to look for any effects of ZYTIGA on your liver.

Driving or using machines

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

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

Looking after your medicine

- Store ZYTIGA in the original container.
- **ZYTIGA 250 mg bottle:** Store below 25°C. Keep the 250 mg tablet bottle tightly closed in order to protect from moisture.
- **ZYTIGA 500 mg blister pack:** Store below 30°C. Keep the 500 mg tablet blister strips inside their carton.

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">• 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 |
|--|---|
| Signs of low blood potassium: <ul style="list-style-type: none">• muscle weakness• muscle twitches• heart palpitations Allergic reactions: | 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 |
|---|-------------------|
| <ul style="list-style-type: none"> ● 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)) <p>Blood and heart problems:</p> <ul style="list-style-type: none"> ● High fat levels in your blood ● Blood in urine ● Chest pain ● Heart beat disorders ● Heart failure ● Rapid heart rate <p>Metabolic and liver issues:</p> <ul style="list-style-type: none"> ● Liver function test increase ● Liver failure (yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting) ● Adrenal gland problems | |

| Serious side effects | What to do |
|--|------------|
| <p>Digestive and stomach issues:</p> <ul style="list-style-type: none"> • Indigestion <p>Muscle and physical discomfort:</p> <ul style="list-style-type: none"> • Muscle pains | |

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 ZYTIGA contains

| | |
|---|--|
| Active ingredient (main ingredient) | abiraterone acetate 250 mg or 500 mg |
| Other ingredients (inactive ingredients) | <p>lactose monohydrate microcrystalline cellulose croscarmellose sodium sodium lauryl sulfate magnesium stearate colloidal silicon dioxide</p> <p>Additional ingredients in 250 mg tablet: povidone</p> <p>Additional ingredients in 500 mg tablet: hypromellose iron oxide black iron oxide red macrogol 3350 polyvinyl alcohol talc titanium dioxide</p> |

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| Potential allergens | lactose monohydrate |
|----------------------------|---------------------|

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

What ZYTIGA looks like

ZYTIGA 250 mg uncoated tablets are white to off-white, oval-shaped tablets, with "AA250" on one side (AUST R 180314).

Each plastic bottle contains 120 tablets.

ZYTIGA 500 mg film-coated tablets are purple, oval-shaped tablets, with "AA" on one side and "500" on the other (AUST R 275372).

ZYTIGA 500 mg tablets are available in (PVdC-PE-PVC/Alu) blister packs of 60 tablets.

Who distributes ZYTIGA

Janssen-Cilag Pty Ltd

1-5 Khartoum Rd

Macquarie Park NSW 2113

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

This leaflet was prepared in October 2025.

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