ZYTIGA® Tablets

abiraterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZYTIGA tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ZYTIGA against the benefits this medicine is expected to have for you.

If you have any concerns about being given ZYTIGA ask your doctor.

Keep this leaflet while you are taking ZYTIGA.

You may need to read it again.

What ZYTIGA is used for

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.

Ask your doctor if you have any questions about why ZYTIGA has been prescribed for you.

This medicine is available only with a doctor's prescription.

ZYTIGA is not addictive.

Before you take ZYTIGA

When you must not use it:

Do not take ZYTIGA:

- if you are allergic (hypersensitive) to abiraterone, or other ingredients of ZYTIGA. See Product Description at the end of this leaflet for a list of ingredients.

Do not take ZYTIGA:

- if the packaging is torn or shows signs of tampering.
- if the expiry date (month and year) printed on the pack has passed. If you take ZYTIGA after the expiry date it may not work.

Do not take ZYTIGA:

- if you are pregnant or maybe potentially pregnant

ZYTIGA is not for use in women and children.

Before you start to use it:

Tell your doctor if you have or have had any 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.

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

High blood pressure and heart problems

ZYTIGA can make high blood pressure or heart failure or low blood potassium 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.

Pregnancy

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.

Taking other medicines:

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.

ZYTIGA might interact with other medicines. 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, 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 you are taking or reduce the dose.

Taking ZYTIGA

How much ZYTIGA to take:

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

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

Instructions:

DO NOT TAKE ZYTIGA WITH FOOD

ZYTIGA should be taken at least two hours after eating and no food should 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.

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 10 mg daily taken according to your doctor's instructions.

What do I do if I forget to take ZYTIGA?

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.

What do I do if I take too much? (overdose):

If you think you or anybody else has taken too much ZYTIGA, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling:

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

While you are taking ZYTIGA

Things you must do:

Do not stop taking ZYTIGA 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 ZYTIGA. 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 your doctor or pharmacist that you are taking ZYTIGA.

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

Things to be careful of

Driving and using machines

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

Side Effects

Like all medicines, ZYTIGA can have side effects. Some of these effects may be serious.

Tell your doctor or pharmacist if you do not feel well while you are being treated with ZYTIGA.

Stop taking ZYTIGA 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 ZYTIGA are diarrhoea, fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures.

Other side effects from ZYTIGA are high fat levels in your blood, liver function test increases, indigestion, blood in urine, chest pain, heart beat disorders, heart failure, rapid heart rate, muscle pains and adrenal gland problems. If these or any other effects occur, talk to your doctor without delay.

If you experience any of these side effects and they worry you, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Other side effects not listed above may also occur in some people.

Product Description

Storage

ZYTIGA tablets should be kept out of reach of children, in a location where the temperature stays below 25°C in the case of the 250 mg bottle and below 30°C in the case of the 500 mg blister pack.

ZYTIGA tablets should be stored in the original container. Keep the 250 mg tablet bottle tightly closed in order to protect from moisture. Keep the 500 mg tablet blister strips inside their carton.

What it looks like:

ZYTIGA 250 mg tablets are white to off-white, oval tablets, with "AA250" on one side. Each plastic bottle contains 120 tablets.

ZYTIGA 500 mg film-coated tablets are purple, oval-shaped, film-coated tablets, debossed with “AA” on one side and “500” on the other. ZYTIGA 500 mg tablets are available in (PVdC-PE-PVC/Alu) blister packs of 60 tablets.

Ingredients

Active ingredient:

- abiraterone acetate 250 mg or 500 mg

Other ingredients:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- povidone
- sodium lauryl sulphate
- magnesium stearate
- colloidal silicon dioxide

Additional ingredients in 500 mg tablet:

- hypromellose
- iron oxide black
- iron oxide red
- macrogol 3350
- polyvinyl alcohol
- talc
- titanium dioxide

Sponsor

JANSSEN-CILAG Pty Ltd

1-5 Khartoum Rd

Macquarie Park

NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

Registration number

250 mg Tablet: AUST R 180314

500 mg Tablet: AUST R 275372

This leaflet was prepared in February 2017

®ZYTIGA is a registered trademark of Janssen-Cilag.