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What ZYTIGA® is used for

ZYTIGA® is indicated with prednisone or prednisolone for the treatment of prostate cancer that has spread to other parts of the body.

How ZYTIGA® works

ZYTIGA® stops your body from making testosterone. Research has shown that testosterone helps to fuel the tumor. Reducing the production of testosterone is important to manage your illness.

Before you use ZYTIGA®

- *When you must not use it*

Pregnancy and lactation

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 pregnant or might be pregnant, wear gloves if you need to touch or handle ZYTIGA® 250 mg uncoated tablets.

Women, infants and children

ZYTIGA® is not for use in women and children.

Kidney disease

ZYTIGA® may be used in patients with kidney disease.

Liver disease

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

- *Before you start to use it*

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

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.

ZYTIGA® may affect your liver. Rarely, failure of the liver to function (called acute liver failure) may occur, which can lead to death. Talk to your doctor if you develop yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting, as these could be signs or symptoms of liver problems. When you are taking ZYTIGA® your doctor will check your blood to look for any effects of ZYTIGA® on your liver.

ZYTIGA® may decrease bone density. Talk to your doctor if you have bone problems.

ZYTIGA® contains lactose. You should not take ZYTIGA® if you have galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

ZYTIGA® contains higher sodium content (1.18 mmol or 27.2 mg) per dose of 4 tablets. Talk to your doctor if you are on a controlled sodium diet.

- *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.

Taking ZYTIGA® with certain other medicines/treatments may result in greater or lesser effects or even side effects from these medicines/treatments. Tell your doctor about everything you are taking or being treated with so that your doctor can tell you whether you can continue the medicines/treatments you are taking or reduce the dose, etc.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because ZYTIGA® may increase the effects of a number of medicines including some medicines for diabetes. Your doctor may want to change the dose of these medicines.

How to use ZYTIGA®

- *How much to use*

The usual daily dose of ZYTIGA® is 1000mg (two 500 mg tablets or four 250 mg tablets) taken as a single dose.

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.

ZYTIGA® tablets must be swallowed whole with water. Do not break the tablets.

- *When to use it*

Do not take ZYTIGA® with food. Take ZYTIGA® 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. - <u>How long to use it</u> Do not stop any treatment unless your doctor tells you to do so - <u>If you forget to use it</u> 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. - <u>If you use too much (overdose)</u> If you accidentally take more than the usual dose, contact your doctor or pharmacist. <i>Special instruction for preparation or administration:</i> Women who are pregnant or women who may be pregnant should not handle ZYTIGA[®] 250 mg uncoated tablets without protection, for example, gloves.	Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give ZYTIGA[®] to anyone else, even if they have the same symptoms or condition as you - <u>Things to be careful of</u> <i>Driving and using machinery</i> It is thought that ZYTIGA[®] will not affect your ability to drive or use any tools or machines Side effects Stop taking ZYTIGA[®] and see a doctor immediately if you notice signs of low blood potassium: muscle weakness, muscle twitches, fast or uneven heartbeats. The most common side effects of ZYTIGA[®] are 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 or irregular heart rate associated with feeling faint or lightheaded, and adrenal gland problems. Other side effects were lung irritation (called allergic alveolitis), breakdown of muscle tissue (called rhabdomyolysis), muscle weakness and/or muscle pain (called myopathy), failure of the liver to function (called acute liver failure), and 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)). If these or any other effects occur, talk to your doctor without delay. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting side effects to medicines (ConSERF) or Vaccines (AEFI)].	- <u>Storage</u> Store ZYTIGA[®] tablets below 30°C. Keep ZYTIGA[®] out of the reach of children. - <u>Disposal</u> Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. Product description - <u>What it looks like</u> ZYTIGA[®] 250 mg uncoated tablets are white to off-white, oval tablets with AA250 on one side ZYTIGA[®] 500mg film-coated tablets are purple, oval-shaped tablets with “AA” on one side and “500” on the other. - <u>Ingredients</u> - Active ingredient Abiraterone acetate - Inactive ingredients ZYTIGA[®] 250 mg uncoated tablets Colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate. ZYTIGA[®] 500mg film-coated tablets Tablet core: colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, silicified microcrystalline cellulose and sodium lauryl sulfate Tablet film-coat: iron oxide black, iron oxide red, macrogol 3350, polyvinyl alcohol, talc and titanium dioxide
While you are using ZYTIGA[®] - <u>Things you must do</u> 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 ZYTIGA[®]. If you are undergoing anesthesia, tell your anesthetist 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. - <u>Things you must not do</u>	Storage and disposal of ZYTIGA[®]	- <u>MAL number</u> ZYTIGA[®] 250 mg uncoated tablets MAL12085056ACRZ ZYTIGA[®] 500mg film-coated tablets MAL20116008ACZ Manufacturer

ZYTIGA® 250 mg uncoated tablets

Patheon Inc.

2100 Syntex Court, Mississauga,
Ontario, L5N 7K9, Canada.

ZYTIGA® 500mg film-coated tablets

Patheon France S.A.S

40 Boulevard de Champaret,
38300 Bourgoin Jallieu,
France.

Product registration holder

Johnson & Johnson Sdn Bhd (3718-D)
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46150, Petaling Jaya, Selangor, Malaysia

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