เอกสารกำกับยาภาษาอังกฤษสำหรับผู้ป่วย

ZYTIGA® (Zye-tee-ga)
(abiraterone acetate)
tablets

What is ZYTIGA?

ZYTIGA is a prescription medicine that is used along with prednisone. ZYTIGA is used to treat men with prostate cancer that has spread to other parts of the body.

It is not known if ZYTIGA is safe and effective in females or children.

Before taking ZYTIGA, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have liver problems
- have diabetes
- have a history of adrenal problems
- have a history of pituitary problems
- are receiving any other treatment for prostate cancer
- are pregnant or plan to become pregnant. ZYTIGA can cause harm to your unborn baby and loss of pregnancy (miscarriage). Females who are or may become pregnant should not handle ZYTIGA uncoated tablets or other ZYTIGA tablets if broken, crushed, or damaged without protection, such as gloves.
- have a partner who is pregnant or may become pregnant.
    - Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with ZYTIGA and for 3 weeks after the last dose of ZYTIGA.
- are breastfeeding or plan to breastfeed. It is not known if ZYTIGA passes into your breastmilk.

Tell your healthcare provider about all the medicines you take or treatments you receive, including prescription and over- the-counter medicines, vitamins, and herbal supplements. ZYTIGA can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ZYTIGA.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ZYTIGA?

- Take ZYTIGA and prednisone exactly as your healthcare provider tells you.

- Take your prescribed dose of ZYTIGA 1 time a day.
- Your healthcare provider may change your dose if needed.
- **Do not change or stop taking your prescribed dose of ZYTIGA or prednisone without talking with your healthcare provider first.**
- Take ZYTIGA tablets as a single dose one time a day on an **empty stomach**. **Do not eat food 2 hours before and 1 hour after taking ZYTIGA.**
- **Do not take ZYTIGA with food.** Taking ZYTIGA with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.
- Swallow ZYTIGA tablets whole. Do not crush or chew tablets.
- Take ZYTIGA tablets with water.
- If you miss a dose of ZYTIGA or prednisone, take your prescribed dose the following day. If you miss more than 1 dose, tell your healthcare provider right away.
- Your healthcare provider will do blood tests to check for side effects.

What are the possible side effects of ZYTIGA?

ZYTIGA may cause serious side effects including:

- **High blood pressure (hypertension), low blood potassium levels (hypokalemia), fluid retention (edema), and irregular heartbeats can happen during treatment with ZYTIGA**. This can be life threatening. To decrease the chance of this happening, you must take prednisone with ZYTIGA exactly as your healthcare provider tells you. Your healthcare provider will check your blood pressure, do blood tests to check your potassium levels, and check for any signs and symptoms of fluid retention every month during treatment with ZYTIGA.

  Tell your healthcare provider if you get any of the following symptoms:

  - dizziness
  - fast or irregular heartbeats
  - feel faint or lightheaded
  - headache
  - confusion
  - muscle weakness
  - pain in your legs
  - swelling in your legs or feet

- **Adrenal problems** may happen if you stop taking prednisone, get an infection, or are under stress.
- **Severe liver problems**. You may develop changes in liver function blood tests. Your healthcare provider will do blood tests to check your liver before treatment with ZYTIGA and during treatment with ZYTIGA. Liver failure may occur, which can lead to death. Tell your healthcare provider right away if you notice any of the following changes:
  - yellowing of the skin or eyes
  - darkening of the urine
  - severe nausea or vomiting
- **Increased risk of bone fracture and death** when ZYTIGA and prednisone or prednisolone, is used in combination with a type of radiation called radium Ra 223 dichloride. Tell your healthcare provider about any other treatments you are taking for prostate cancer.
- **Severe low blood sugar (hypoglycemia).** Severe low blood sugar with ZYTIGA can

happen in people who have diabetes and take certain antidiabetic medicines. You and your healthcare provider should check your blood sugar levels regularly during treatment with ZYTIGA and after you stop treatment. Your healthcare provider may also need to change the dose of your antidiabetic medicines. Signs and symptoms of low blood sugar may include.

- headache
- drowsiness
- weakness
- dizziness
- confusion
- irritability
- hunger
- fast heartbeat
- sweating
- feeling jittery

The most common side effects of ZYTIGA include:

- feeling very tired
- joint pain
- high blood pressure
- nausea
- swelling in your legs or feet
- low blood potassium levels
- hot flushes
- diarrhea
- vomiting
- infected nose, sinuses, or throat (cold)
- cough
- headache
- low red blood cells (anemia)
- high blood cholesterol and triglycerides
- high blood sugar levels
- certain other abnormal blood tests

ZYTIGA may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of ZYTIGA.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA.

How should I store ZYTIGA?

- Store ZYTIGA below 30°C. See expiry date on the outer pack.

Keep ZYTIGA and all medicines out of the reach of children.

General information about the safe and effective use of ZYTIGA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

Do not use ZYTIGA for a condition for which it was not prescribed. Do not give ZYTIGA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about ZYTIGA that is written

for health professionals.

What are the ingredients of ZYTIGA?

Active ingredient: abiraterone acetate

Inactive ingredients:

500 mg film-coated tablets: colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, silicified microcrystalline cellulose, and sodium lauryl sulfate. The film-coating contains iron oxide black, iron oxide red, macrogol 3350, polyvinyl alcohol, talc, and titanium dioxide.

250 mg uncoated tablets: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate.

Nature and contents of container:

500 mg film-coated tablets: available in blister packs for a total of 60 tablets, individual (PVdC-PE-PVC/alu) blister strips are packed inside a folding carton.

250 mg uncoated tablets: 120 tablets available in high-density polyethylene bottles.

Warning according to the announcement of Ministry of Public Health

This medicinal product may cause serious harm. It must be used only under physician's supervision.

	Manufactured by	**Market authorization number**	**Date of authorization**
ZYTIGA 250 MG	Patheon Inc. Ontario, Canada	1C 88/56 (N)	Initial Authorization Date: 4 June 2013 SMP Released Approval: 31 August 2017
ZYTIGA 250 MG	Patheon S.A.S. Bourgoin Jallieu, France	1C 15069/63 (N)	Initial Authorization Date: 28 March 2018 SMP Released Approval: N/A Renewal date: 10 March 2020
ZYTIGA 500 MG (Film-coated tablets)	Patheon S.A.S. Bourgoin Jallieu,	1C 15062/61 (N)	Initial Authorization Date: 16 August 2018

	France		SMP Released Approval: N/A

For more information, please see full prescribing information at https://ndi.fda.moph.go.th/

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To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

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