PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZYTIGA® 250 mg tablets

ZYTIGA® 500 mg film-coated tablets

abiraterone acetate

Each ZYTIGA 250 mg tablet contains 198,7 mg of lactose monohydrate and 6,8 mg of sodium.

Each ZYTIGA 500 mg film-coated tablet contains 253,2 mg of lactose monohydrate and 13,5 mg of sodium.

Read all of this leaflet carefully before you start using ZYTIGA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZYTIGA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZYTIGA is and what it is used for
2. What you need to know before you take ZYTIGA

3. How to take ZYTIGA
4. Possible side effects
5. How to store ZYTIGA
6. Contents of the pack and other information

1. What ZYTIGA is and what it is used for

ZYTIGA contains a medicine called abiraterone acetate. ZYTIGA is used to treat prostate cancer in adult men that has spread to other parts of the body.

2. What you need to know before you take ZYTIGA

Do not take ZYTIGA

- if you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or might be pregnant. If you are pregnant or might be pregnant, you should wear gloves if you need to touch or handle ZYTIGA 250 mg tablets.
- if you have moderate or severe impairment of your liver function. ZYTIGA may affect your liver. Failure of the liver to function (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.
- if you are taking medicines containing rifampicin.
- if you are a woman. ZYTIGA is for use in male patients only.
- in combination with Ra-223 (which is used to treat prostate cancer).

Do not take ZYTIGA if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Take special care with ZYTIGA:

- if you have been told you have high blood pressure or heart failure or a low blood potassium (See section “Do not take”).
- if you have had other heart or blood vessel problems.
- if you have liver problems (See section “Do not take”).
- 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 have gained weight rapidly.
- if you have swelling in the feet, ankles, or legs.
- about the need to take this medicine with prednisone or prednisolone.
- about possible effects on your bones.
- if you have high blood sugar.
- if you require vaccination or have come into contact with someone who has received a vaccine.
- if you have tuberculosis.
- if you have HIV.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

ZYTIGA may affect your liver, and you may not have any symptoms. When you are taking ZYTIGA, your doctor will check your blood periodically to look for any effects on your liver.

Children and adolescents

ZYTIGA is **not** for use in children and adolescents.

Other medicines and ZYTIGA

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

ZYTIGA may increase the effects of a number of medicines including heart medicines, tranquilisers, and others. Your doctor may want to change the dose of these medicines. Also, some medicines may increase or decrease the effects of ZYTIGA. This may lead to side effects or to ZYTIGA not working as well as it should.

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 healthcare provider if you monitor your blood sugar while taking a medicine for diabetes and notice a drop in your blood sugar.

Tell your doctor if you are taking phenytoin, carbamazepine, rifabutin, phenobarbitone or St. John's wort because these medicines may decrease the effect of ZYTIGA. Tell your doctor if you are taking spironolactone as spironolactone may cause prostate specific antigen (PSA) levels to increase. Use with ZYTIGA is not recommended.

ZYTIGA with food

- **ZYTIGA must not be taken with food.**
- **Take ZYTIGA tablets 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.**
- ZYTIGA tablets must be swallowed whole with water.
- Taking ZYTIGA with food causes more of ZYTIGA to be absorbed by the body than is needed and this may cause serious side effects.

Pregnancy and Breastfeeding

ZYTIGA is not for use in women.

- Women who are pregnant or breastfeeding or women who may be pregnant (including healthcare professionals) should wear gloves if they need to touch or handle ZYTIGA 250 mg tablets.
- This medicine may cause harm to the unborn child if it is taken by women who are pregnant.
- If you are having sex with a woman who can become pregnant, use a condom and another effective birth control method.
- If you are having sex with a pregnant woman, use a condom to protect the unborn child.

Driving and using machines

ZYTIGA is not likely to affect your ability to drive or use any tools or machines.

ZYTIGA contains lactose and sodium

ZYTIGA contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Patients with the rare hereditary condition of lactose intolerance, e.g. galactosaemia should not take ZYTIGA.

ZYTIGA 250 mg also contains approximately 27 mg of sodium in a four tablet daily dose. ZYTIGA 500 mg also contains approximately 27 mg of sodium in a two tablet daily dose. To be taken into consideration by patients on a controlled sodium diet.

3. How to take ZYTIGA

Do not share medicines prescribed for you with any other person.

Always take ZYTIGA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The usual dose of ZYTIGA is 1000 mg (two 500 mg tablets or four 250 mg tablets) once a day, taken as a single dose on an empty stomach.

When you take ZYTIGA your doctor will also prescribe another medicine called prednisone or prednisolone. This is to lower your chances of getting high blood pressure, having too much water in your body (fluid retention), or having reduced levels of a chemical known as potassium in your blood.

- You need to take prednisone or prednisolone every day while you are taking ZYTIGA.

- Do not stop taking prednisone or prednisolone unless your doctor tells you to.
- The amount of prednisone or prednisolone you take may need to change if you have a medical emergency. Your doctor will tell you if you need to change the amount of prednisone or prednisolone you take.

Your doctor may also prescribe other medicines while you are taking ZYTIGA and prednisone or prednisolone.

Taking ZYTIGA

- Take ZYTIGA by mouth.
- **Do not take ZYTIGA with food**.
- **Take ZYTIGA tablets 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.
- Swallow the tablets whole with water.
- Do not break the tablets.
- ZYTIGA is taken with a medicine called prednisone or prednisolone. Take the prednisone or prednisolone exactly as your doctor has told you.

Your doctor will tell you how long your treatment with ZYTIGA will last. Do not stop any treatment unless your doctor tells you to do so. If you have the impression that the effect of ZYTIGA is too strong or too weak, tell your doctor or pharmacist.

If you take more ZYTIGA than you should

If you take more ZYTIGA than you should, talk to your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ZYTIGA

- If you forget to take ZYTIGA or prednisone or prednisolone, take your normal dose the following day.
- If you forget to take ZYTIGA or prednisone or prednisolone for more than one day, talk to your doctor without delay.
- Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZYTIGA

Do not stop taking ZYTIGA or prednisone or prednisolone unless your doctor tells you to.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

ZYTIGA can cause side effects. Not all side effects reported for ZYTIGA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZYTIGA, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking ZYTIGA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty swallowing or breathing, swollen face, lips, tongue or throat, or an itchy rash.

- Muscle weakness, muscle twitches, fast or uneven heart beats. These may be signs that the level of potassium in your blood is low.
- Yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting. These may be signs or symptoms of liver problems.

These are all serious side effects. If you have them, you may have had a serious reaction to ZYTIGA. You may need urgent medical attention or hospitalisation.

Other side effects include:

Frequent side effects

- Excessive fluid in the soft tissues of your legs or feet (swollen hands, ankles or feet),
- Low blood potassium (main symptoms include: low blood pressure, dizzy spells, cold hands and feet, feeling tired, leg cramps, weakness, and constipation. It also increases the risk of an abnormal heart rhythm),
- High blood pressure,
- Urinary tract infection,
- Diarrhoea,
- High fat levels in your blood,
- Increased liver function test levels,
- Chest pain,
- Irregular heartbeat (atrial fibrillation),
- Heart failure,
- Rapid heart rate,
- Severe infections called sepsis,
- Bone fractures,

- Indigestion,
- Blood in urine,
- Rash.

Less frequent side effects:

- Adrenal gland problems,
- Abnormal heart rhythm (dysrythmia),
- Muscle weakness and/or muscle pain,
- Lung inflammation (also called allergic alveolitis),
- Breakdown of muscle tissue (rhabdomyolysis),
- Failure of the liver to function (acute liver failure),
- Heart attack,
- Changes in ECG – electrocardiogram (QT prolongation).

Bone loss may occur in men treated for prostate cancer. ZYTIGA in combination with prednisone or prednisolone may increase bone loss.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/index/8

By reporting side effects, you can help provide more information on the safety of ZYTIGA.

Alternatively, you may report side effects experienced with ZYTIGA directly to Janssen Pharmaceutica (see section 'Holder of the Certificate of Registration' for contact details or visit www.janssen.com).

5 How to store ZYTIGA

- Store all medicines out of reach of children.
- Store at or below 30 °C. Keep well closed.
- Do not use this medicine after the expiry date stated on the label / carton. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). These measures will help protect the environment.

6 Contents of the pack and other information

The active substance is abiraterone acetate.

Each ZYTIGA 250 mg tablet contains 250 mg abiraterone acetate. The other ingredients are colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and sodium lauryl sulfate (see section 2, "ZYTIGA contains lactose and sodium").

Each ZYTIGA 500 mg film-coated tablet contains 500 mg abiraterone acetate. The other ingredients are microcrystalline cellulose (silicified), croscarmellose sodium, hypromellose

2910 (15 mPa.S), lactose monohydrate, magnesium stearate, colloidal anhydrous silica, sodium lauryl sulfate, polyvinyl alcohol, titanium dioxide, macrogol 3350, talc, iron oxide red and iron oxide black (see section 2, “ZYTIGA contains lactose and sodium”).

What ZYTIGA looks like and contents of the pack

ZYTIGA® 250 mg tablets:

ZYTIGA® 250 mg uncoated tablets are white to off white, oval tablets 16 mm long, debossed with AA250 on one side.

ZYTIGA 250 mg tablets are supplied in high density polyethylene round white bottles fitted with a white polypropylene cap and packed into an outer carton. Package size is 120 tablets.

ZYTIGA 500 mg film-coated tablets:

ZYTIGA® 500 mg tablets are purple, oval-shaped, film-coated tablets (20 mm long by 10 mm wide), debossed with “AA” on one side and “500” on the other side.

ZYTIGA 500 mg tablets are available in blister packs of 60 tablets. Individual PVdC-PE-PVC/aluminium blister strips are packed inside a folding carton.

Holder of certificate of registration

JANSSEN PHARMACEUTICA (PTY) LTD

(Reg No.: 1980/011122/07)

2 Medical Road,

Halfway House, Midrand, 1685

Tel: +27 (0) 11 518 7000

ra-medinfoemmarkets@its.jnj.com

This leaflet was revised on

15 November 2022

Registration numbers

ZYTIGA 250 mg tablets: 46/21.12/0379

ZYTIGA 500 mg tablets: 52/21.12/0284

ZYTIGA 250 mg tablets:

Namibia Reg. No.: 15/21.12/0085

NS 2

Zimbabwe Reg. No.: 2016/9.5.2/5202

PP

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.