PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZYBERA 500 mg film-coated tablets

Abiraterone acetate

Contains sugar (lactose monohydrate) 90 mg per tablet

Read all of this leaflet carefully before you start taking ZYBERA 500 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZYBERA 500 mg 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 ZYBERA 500 mg IS AND WHAT IT IS USED FOR

ZYBERA 500 mg contains a medicine called abiraterone acetate. It is used to treat prostate cancer in adult men that has spread to other parts of the body.

Your doctor will also prescribe another medicine called prednisone or prednisolone.

ZYBERA 500 mg stops your body from making testosterone; this can slow the growth of prostate cancer.

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When ZYBERA 500 mg is prescribed for the early stage of disease where it is still responding to hormone therapy, it is used with a treatment that lowers testosterone (androgen deprivation therapy).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZYBERA 500 mg

Do not take ZYBERA 500 mg:

- If you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of ZYBERA 500 mg (listed in section 6).
- if you are pregnant or breastfeeding your baby. If you are pregnant or might be pregnant, you should wear gloves if you need to touch or handle ZYBERA 500 mg 500 mg tablets.
- if you have moderate or severe impairment of your liver function. ZYBERA 500 mg 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. ZYBERA 500 mg is for use in male patients only.
- in combination with Ra-223 (which is used to treat prostate cancer).

Warnings and precautions

Take special care with ZYBERA 500 mg:

Tell your doctor:

- 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 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

Blood monitoring

ZYBERA 500 mg may affect your liver, and you may not have any symptoms. When you are taking ZYBERA 500 mg your doctor will check your blood periodically to look for any effects on your liver.

Children and adolescents

ZYBERA 500 mg is not for use in children and adolescents.

Other medicines and ZYBERA 500 mg

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are already taking medicines that contain any of the following:

- herbal medicines (e.g., St John's wort), tranquilisers – your doctor may want to change the dose of these medicines
- phenytoin, carbamazepine, phenobarbitone (used for epilepsy, seizures)
- rifampicin, rifabutin, rifapentine (tuberculosis treatment)
- known to increase the risk of heart rhythm problems [e.g., methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics (used for serious mental illnesses)]
- used to treat heart rhythm problems (e.g., quinidine, disopyramide, procainamide, amiodarone and sotalol, dofetilide, ibutilide)
- spironolactone (used for treatment of heart failure).

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ZYBERA 500 mg with food

ZYBERA 500 mg **must not be taken with food.**

Taking ZYBERA 500 mg with food may cause side effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking ZYBERA 500 mg . ZYBERA 500 mg is not indicated in women.

ZYBERA 500 mg is not for use in women.

ZYBERA 500 mg 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

This medicine is not likely to affect your being able to drive and use any tools or machines.

It is not always possible to predict to what extent ZYBERA 500 mg may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which ZYBERA 500 mg affects you.

ZYBERA 500 mg contains lactose monohydrate

ZYBERA 500 mg contains sugar (lactose monohydrate) 90 mg per tablet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZYBERA 500 mg.

ZYBERA 500 mg also contains less than 1 mmol (or 23 mg) sodium per dose that is to say it is essentially 'sodium-free'.

3. HOW TO TAKE ZYBERA 500 mg

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

Always take ZYBERA 500 mg exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 000 mg (two 500 mg tablets) once a day.

When you take ZYBERA 500 mg 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 ZYBERA 500 mg.
- 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. Do not stop taking prednisone or prednisolone unless your doctor tells you to.

Taking ZYBERA 500 mg

Take ZYBERA 500 mg by mouth.

Do not take ZYBERA 500 mg with food.

Take ZYBERA 500 mg at least one hour before or at least two hours after eating (see section 2, "ZYBERA 500 mg with food"). Taking ZYBERA 500 mg with food causes more of ZYBERA 500 mg 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.

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Use in children

ZYBERA 500 mg is **not** for use in children.

Your doctor will tell you how long your treatment with ZYBERA 500 mg will last. If you have the impression that the effect of ZYBERA 500 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more ZYBERA 500 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ZYBERA 500 mg

Do not take a double dose to make up for forgotten individual doses.

If you forget to take ZYBERA 500 mg or prednisone or prednisolone, take your normal dose PRODUCT NAME] [the following day.

If you forget to take ZYBERA 500 mg or prednisone or prednisolone for more than one day, talk to your doctor without delay.

If you stop taking ZYBERA 500 mg

Do not stop taking ZYBERA 500 mg 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

ZYBERA 500 mg can have side effects

Not all side-effects reported for ZYBERA 500 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZYBERA 500 mg, please consult your healthcare provider for advice.

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If any of the following happens, stop taking ZYBERA 500 mg tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZYBERA 500 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- severe infections called sepsis
- muscle weakness, muscle twitches or a pounding heartbeat (palpitations). These may be signs that the level of potassium in your blood is low (adrenal gland problems)
- heart attack, changes in ECG - electrocardiogram (QT prolongation)
- chest pain, irregular heartbeat (atrial fibrillation)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- urinary tract infection
- high fat levels in your blood
- fast heartbeat
- high blood pressure
- diarrhoea
- indigestion

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- liver function test increases
- blood in urine
- fluid in your legs or feet
- bone fractures

Less frequent side effects

- abnormal heart rhythm (dysrhythmia)
- lung irritation (also called allergic alveolitis)
- failure of the liver to function (also called acute liver failure)
- liver necrosis and decrease in liver size
- muscle pain
- a condition in which skeletal muscle is broken down, releasing muscle enzymes and electrolytes from inside the muscle cell (rhabdomyolysis)

Frequency unknown:

- Non-alcoholic fatty liver disease (NAFLD)
- cirrhosis, a chronic disease of the liver marked by a deterioration (degeneration) of cells, inflammation, and thickening of liver cell tissue
- death of most or all of the cells in the liver (liver necrosis)
- liver disease.

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

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 the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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By reporting side effects, you can help provide more information on the safety of ZYBERA 500 mg .

5. HOW TO STORE ZYBERA 500 mg

Store all medicine out of reach of children.

Store at or below 25 °C.

Store in the original package until required for use.

Do not use the tablets after the expiry date shown on the container.

Return the expired medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ZYBERA 500 mg contains

The active ingredient is abiraterone acetate. Each film-coated tablets contains 500 mg abiraterone acetate.

The other ingredients are:

Tablet core: croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, povidone, silica colloidal anhydrous, sodium laurilsulfate, magnesium stearate.

Tablet coating ZYBERA 500 mg: Opadry II 85F32410 yellow consisting of iron Oxide Yellow (E172), polyvinyl alcohol (part hydrolysed), macrogol 4000/PEG (E1521), titanium dioxide (E171) and talc.

What ZYBERA 500 mg looks like and contents of the pack

ZYBERA 500 mg is a yellow, oblong film-coated tablet, debossed with “A436” on one side and plain on the other side.

ZYBERA 500 mg is packaged in PVC/ACLAR/PVC – aluminium blister pack. The blisters strips are further packed into carton boxes with a leaflet included.

Pack size is 60 tablets.

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Holder of Certificate of Registration

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