PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

ABITATE 250 film-coated tablets

ABITATE 500 film-coated tablets

Abiraterone acetate

Contains sugar.

Each ABITATE 250 tablet contains 126,60 mg lactose monohydrate.

Each ABITATE 500 tablet contains 253,20 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ABITATE

- 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.
- ABITATE 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 ABITATE is and what it is used for

2. What you need to know before you take ABITATE

3. How to take ABITATE

4. Possible side effects

5. How to store ABITATE

6. Contents of the pack and other information

1. What ABITATE is and what it is used for

ABITATE 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.

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

When ABITATE 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 ABITATE

Do not take ABITATE:

- If you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of ABITATE (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 ABITATE tablets.
- if you have moderate or severe impairment of your liver function. ABITATE 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. ABITATE is for use in male patients only.
- in combination with radium 223 dichloride (Ra-223) (which is used to treat prostate cancer).

Warnings and precautions

Take special care with ABITATE :

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 or low 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 have taken a medicine known as ketoconazole in the past for prostate cancer.

The safety and efficacy of concomitant use of ABITATE with cytotoxic chemotherapy has not been established.

Decrease in red blood cells, reduced sex drive (libido), muscle weakness and/or muscle pain may occur.

ABITATE must not be given in combination with Ra-223 due to a possible increase in the risk of bone fracture or death.
If you plan to take Ra-223 following treatment with ABITATE and prednisone/prednisolone, you must wait 5 days before starting treatment with Ra-223.

Blood monitoring

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

Children and adolescents

ABITATE is not for use in children and adolescents.

Other medicines and ABITATE

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)
- paroxetine, metoprolol, propranolol, desipramine, venlafaxine, haloperidol, risperidone, propafenone, flecainide
- pain medicine containing codeine, oxycodone and tramadol
- 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 and eplenerone (used for treatment of heart failure)
- medicines used to treat diabetes – low blood sugar may occur to patients with pre-existing diabetes receiving pioglitazone or repaglinide
- some medicines for fungal infections such as ketoconazole
- cough medicines such as dextromethorphan
- medicines that help you breathe when you have lung diseases (e.g., asthma, bronchitis, emphysema), such as theophylline.

ABITATE with food

ABITATE must not be taken with food.

Do not take ABITATE with food, as it affects the way the medicine is absorbed.

Taking ABITATE 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 ABITATE.

ABITATE is not for use in women.

ABITATE may cause harm to the unborn child if it is taken by women who are pregnant.

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 ABITATE.

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 ABITATE 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 ABITATE affects you.

ABITATE contains lactose monohydrate

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

ABITATE 250 & 500 contains 23,5 mg sodium (main component of cooking/table salt) in each 1 g dose administered. This is equivalent to 1,18 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take ABITATE

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

Always take ABITATE 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 (four 250 mg or two 500 mg tablets) once a day.

When you take ABITATE 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 ABITATE.
- 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 ABITATE

Take ABITATE by mouth.

Do not take ABITATE with food.

Take ABITATE at least one hour before or at least two hours after eating (see section 2, “ABITATE with food”). Taking ABITATE with food causes more of ABITATE 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.

Use in children

ABITATE is **not** for use in children.

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

If you take more ABITATE 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 ABITATE

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

If you stop taking ABITATE

Do not stop taking ABITATE 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

ABITATE can have side effects

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

If any of the following happens, stop taking ABITATE 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 ABITATE. 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
- liver function test increases
- blood in urine
- fluid in your legs or feet
- bone fractures
- chest pain (angina pectoris)
- heart failure
- rash.

Less frequent side effects

- abnormal heart rhythm (dysrhythmia)
- 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)
- adrenal gland problems (related to salt and water problems).

Side effects with unknown frequency

- lung irritation (also called allergic alveolitis).

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

5. How to store ABITATE

Store all medicine out of reach of children.

Store below 25 °C. Protect from moisture.

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 ABITATE contains

The active ingredient is abiraterone acetate. Each film-coated tablets contains 250 ng or 500 mg abiraterone acetate.

The other ingredients are:

Core Ingredients: Lactose monohydrate, croscarmellose sodium, hypromellose 2910 (15 mPa.s), sodium laurilsulfate, silicified microcrystalline cellulose, silica, colloidal anhydrous, magnesium stearate.

Coating Ingredients (250 mg) : Ready to use coating material (White Colour) consisting of poly vinyl alcohol, titanium dioxide, macrogol 3350, talc.

Coating Ingredients (500 mg) : Ready to use coating material (Purple Colour) consisting of poly vinyl alcohol, titanium dioxide, macrogol 3350, talc, iron oxide red, iron oxide black.

What ABITATE looks like and contents of the pack

ABITATE 250 : White to off white, oval-shaped, film-coated tablets plain on both sides.

ABITATE 500 : Purple, oval-shaped, film-coated tablets with score line on one side and plain on other side.

ABITATE 250 & 500 is packed in

- PVC/PE/PVDC & Alu blister pack. Each blister contains 10 tablets.
- White opaque HDPE container closed with white opaque polypropylene child resistant closure.

The blisters strips and HDPE container are further packed into carton boxes with a leaflet included.

Pack size: 60 or 120 tablets.

Holder of Certificate of Registration

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ABITATE 250: 58/21.12/0124

ABITATE 500: 58/21.12/0125

Access to the corresponding Professional Information

An electronic copy of the Professional Information (PI) is available on the Equity website http://www.equitypharmaceuticals.co.za or http://www.sahpra.org.za.