

Proprietary name:	ABIKEM
Dosage form:	Tablets
Active Ingredient:	Abiraterone acetate
Strength per dosage unit:	250 mg per tablet

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### 1.3.2 PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

S4

#### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**ABIKEM** Tablets

250 mg of abiraterone (as acetate) per tablet.

Contains sugar.

#### Read all of this leaflet carefully before you start taking **ABIKEM**.

- 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.
- **ABIKEM** 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 **Abikem** is and what it is used for
2. What you need to know before you <take> <use> **Abikem**
3. How to <take> <use> **Abikem**
4. Possible side effects
5. How to store **Abikem**
6. Contents of the pack and other information

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## 1. WHAT ABIKEM IS AND WHAT IT IS USED FOR:

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

When **ABIKEM** 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).

When you take **ABIKEM** 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.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ABIKEM

### Do not take **ABIKEM**:

- if you are allergic to abiraterone acetate or any of the other ingredients of **ABIKEM** (listed in section 6).
- if you are a woman, especially if pregnant. **ABIKEM** is for use in male patients only.
- if you are taking rifampicin
- if you have severe liver damage.
- in combination with Ra-223 (which is used to treat prostate cancer).

Do not take **ABIKEM** 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

Talk to your doctor or pharmacist before taking **ABIKEM**.

Take special care with **ABIKEM**:

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- if you have liver problems;
- if you have been told you have high blood pressure or heart failure or low blood potassium (low blood potassium may increase the risk of heart rhythm problems);
- if you have had other heart or blood vessel problems;
- if you have an irregular or rapid heart rate;
- if you have shortness of breath;
- if you have gained weight rapidly;
- if you have swelling in the feet, ankles, or legs;
- if you have taken a medicine known as ketoconazole in the past for prostate cancer;
- about the need to take this medicine with prednisone or prednisolone;
- about possible effects on your bones;
- if you have high blood sugar.

Tell your doctor if you have been told you have any heart or blood vessel conditions, including heart rhythm problems (dysrhythmia), or are being treated with medicines for these conditions.

Tell your doctor if you have 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.

Rarely, failure of the liver to function (called acute liver failure) may occur, which can lead to death. Decrease in red blood cells, reduced sex drive (libido), muscle weakness and/or muscle pain may occur.

**ABIKEM** 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 **ABIKEM** and prednisone/prednisolone, you must wait 5 days before starting treatment with Ra-223.

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

### **Blood Monitoring:**

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

### **Children and adolescents:**

**ABIKEM** is not for use in children and adolescents. If **ABIKEM** is accidentally ingested by a child or adolescent, go to the hospital immediately and take the package leaflet with you to show to the emergency doctor.

### **Other medicines and ABIKEM:**

Always tell your doctor or pharmacist if you are taking any other medicines. (This includes all complementary and traditional medicines).

Tell your doctor if you are taking any of the following:

- Medicines whose effect is increased by **ABIKEM** such as heart medicines, tranquilizers and herbal medicines such as St. John's wort.

Your doctor may want to change the dose of these medicines. Also, some medicines may increase or decrease the effects of **ABIKEM**. This may lead to side effects or to **ABIKEM** not working as well as it should.

- Androgen deprivation treatment may increase the risk of heart rhythm problems. Tell your doctor if you are receiving the following:
  - medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol);

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- medicines 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)].

### **ABIKEM with food and drink**

**ABIKEM** must not be taken with food (see section 3, “Taking this medicine” ).

Taking **ABIKEM** with food may cause side effects.

### **Pregnancy and breast-feeding**

**ABIKEM** is not for use in women.

**ABIKEM** 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**

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

### **ABIKEM contains:**

**ABIKEM** contains a sugar called lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **ABIKEM**.

## **3. HOW TO TAKE ABIKEM**

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

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Always take **ABIKEM** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is 1,000 mg (four tablets) once a day

### **Taking ABIKEM:**

Take **ABIKEM** by mouth.

Do not take **ABIKEM** with food.

Take **ABIKEM** at least two hours after eating and do not eat anything for at least one hour after taking ABIKEM (see section 2, "**ABIKEM** with food").

Swallow the tablets whole with water. Do not break the tablets.

**ABIKEM** is taken with a medicine called prednisone or prednisolone. Take the prednisone or prednisolone exactly as your doctor has told you.

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

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.

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

### **If you take more ABIKEM than you should:**

If you take more than you should, talk to your doctor or go to a hospital immediately.

### **If you forget to take ABIKEM:**

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If you forget to take **ABIKEM** or prednisone or prednisolone, take your usual dose the following day.

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

### **If you stop taking ABIKEM**

Do not stop taking **ABIKEM** or prednisone or prednisolone unless your doctor tells you to.

If you have any further questions on the use of **ABIKEM**, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

**ABIKEM** can have side effects.

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

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

*Frequent side-effects:* Heart attack, pounding heartbeat (palpitations)

*Less frequent side-effects:* Muscle weakness, muscle twitches. These may be signs that the level of potassium in your blood is low. Liver failure.

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

*Frequent side-effects:* Fluid in your legs or feet, low blood potassium, liver function test increases, high blood pressure, urinary tract infection, diarrhoea, high fat levels in your blood, chest pain,

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irregular heart beat (atrial fibrillation), heart failure, angina, rapid heart rate, severe infections called sepsis, bone fractures, indigestion, blood in urine, rash.

*Less frequent side-effects:* Adrenal gland problems (related to salt and water problems), abnormal heart rhythm (arrhythmia), muscle pain, lung irritation (also called allergic alveolitis).

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

Tell your doctor if you notice any of the following:

*Frequency unknown:* changes in ECG - electrocardiogram (QT prolongation), bone loss may occur in men treated for prostate cancer. **ABIKEM** 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.

### **Reporting of side effects:**

If you get side effects, talk to your <doctor><or><,><pharmacist><or nurse>. You can also report side effects to SAHPRA via the “**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 **ABIKEM**.

## **5. HOW TO STORE ABIKEM**

Store at or below 25 °C (Room temperature).

Keep the bottle tightly closed.

Keep this medicine out of reach of children.

Do not use this medicine after the expiry date stated on the carton and the blister.

Do not throw away any medicines in drains or sewage systems.

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Return all unused medicine to the pharmacist.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What ABIKEM contains:**

The active ingredient is 250 mg of abiraterone acetate per tablet.

The other ingredients are colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulphate.

### **Pack information:**

HDPE bottle pack with white Child Resistance Closure with heat seal and pulp liner for induction seal. The HDPE bottle pack may either be placed in an outer cardboard carton or provided without a carton based on commercial requirement.

### **What ABIKEM looks like and contents of the pack**

White to off white oval shaped tablets debossed with "A" on one side "250" on other side.

Pack sizes: 120 tablets

### **Holder of Certificate of Registration**

Ascend Laboratories (Pty) Ltd.

R21 Corporate Park,

121 Sovereign Drive, Block A, Office 202

Irene Ext. 30, Centurion, 0157

**This leaflet was last revised in**

**Application Numbers**

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### **Access to the corresponding Professional Information**

The professional information will be included in each unit pack of the product.