

**SCHEDULING STATUS**

S4

**ABITIG 250 mg tablets****Abiraterone acetate****Contains sugar (164,75 mg lactose monohydrate per tablet)****Read all of this leaflet carefully before you start taking ABITIG.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ABITIG 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 ABITIG is and what it is used for**
2. **What you need to know before you take ABITIG**
3. **How to take ABITIG**
4. **Possible side effects**
5. **How to store ABITIG**
6. **Contents of the pack and other information.**

**1. What ABITIG is and what it is used for**

ABITIG contains a medicine called abiraterone acetate. ABITIG stops your body from making testosterone; this can slow the growth of cancer tissue in your prostate and elsewhere. ABITIG in combination with other medicines is used to treat prostate cancer in adult men which is in an advanced stage and has spread to other parts of the body.

## 2. What you need to know before you take ABITIG

### Do not take ABITIG:

- If you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of ABITIG (listed in section 6)
- If you are pregnant, trying to get pregnant or may potentially be pregnant, suspect that you are pregnant or if you are breastfeeding your baby
- If you have severe liver problems
- If you are a woman. ABITIG is for use in male patients only
- If you are taking rifampicin (used to treat tuberculosis (TB))
- In combination with  $^{223}\text{Ra}$  (radium 223), which is used to treat prostate cancer

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

### Warnings and precautions:

#### Take special care with ABITIG:

- Women (or health care providers) who are pregnant or may be pregnant should not handle ABITIG without gloves.

#### Tell your doctor or pharmacist:

- If 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, including heart rhythm problems, or are being treated with medicines for these conditions.
- If you have chest pain (angina).
- If you have an irregular or rapid heart rate.
- If you recently had a heart attack.
- If you have swelling in the feet, ankles, or legs.

- If you have severe kidney problems.
- If you have liver problems.
- If you are undergoing a stressful event while taking ABITIG in combination with prednisone and prednisolone.
- If you have weakened bones (decreased bone density). Taking ABITIG in combination with prednisone or prednisolone could have an effect on your bones.
- If you have taken a medicine known as ketoconazole in the past for prostate cancer.
- If you have high blood sugar.
- If you are on chemotherapy.
- If you have gained weight rapidly.
- If you have yellowing of the skin or eyes, darkening of the urine, or severe nausea or vomiting whilst taking ABITIG, as these could be signs or symptoms of acute liver problems, which may be fatal.
- If you have anaemia (decrease in red blood cells). You may start feeling tired and weak, have pale skin, suffer from shortness of breath, chest pain, get frequent infections, headaches, or feel dizzy.
- If you experience reduced sex drive (libido).
- If you experience muscle weakness and/or muscle pain or are taking medicines known to cause muscle weakness.

If you receive radiotherapy, ABITIG must not be given in combination with radium ( $^{223}\text{Ra}$ ) due to a possible increase in the risk of bone fracture or death.

If you plan to receive  $^{223}\text{Ra}$  following treatment with ABITIG and prednisone/prednisolone, you must wait 5 days before starting treatment with  $^{223}\text{Ra}$ .

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

**Blood monitoring**

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

**Children and adolescents:**

ABITIG is not for use in children and adolescents. If ABITIG 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 ABITIG:**

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

Tell your doctor or pharmacist if you are currently using any of the following medicines:

*Avoid using the following medicines, which are strong CYP3A4 inducers with ABITIG:*

- phenytoin, carbamazepine (used to treat epilepsy)
- rifampicin, rifabutin, rifapentine (used to treat TB)
- phenobarbital (used to treat anxiety and certain types of seizures (fits))
- St John's wort (used to treat depression)

*The following medicine causes an increased effect of the medicine when used in combination with ABITIG:*

- dextromethorphan (used to treat cough from smoking or long-term breathing problems).

*Your doctor may reduce the dose of the following medicines (which have a narrow therapeutic index and are metabolised by CYP2D6):*

- metoprolol (used to treat high blood pressure and angina (chest pain))
- propranolol (used to treat high blood pressure, irregular heartbeats, shaking (tremors), social anxiety)
- desipramine, venlafaxine (used to treat depression)
- haloperidol, risperidone (used to treat psychosis, a severe mental disorder)

- propafenone, flecainide (used to treat heart rhythm disorders)
- codeine, oxycodone, tramadol used to treat mild to moderate pain)

*Androgen deprivation treatment may increase the risk of heart rhythm problems. Consult your doctor if you are receiving any of the following:*

- quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide (used to treat heart rhythm disorders)
- methadone (used to treat moderate pain)
- moxifloxacin (an antibiotic used to treat bacterial infections)
- antipsychotic medicines (used to treat mental health problems)

*The following medicine may increase prostate specific antigen (PSA) levels and should not be used in combination with ABITIG:*

- spironolactone (used to treat high blood pressure and heart failure)

#### **ABITIG with food:**

Taking ABITIG with food causes more of ABITIG to be absorbed by the body than is needed and this may cause serious side effects (see section 3, "How to take ABITIG").

#### **Pregnancy and breastfeeding:**

ABITIG is not indicated for use in women.

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

Women who are pregnant, breastfeeding or women who may be pregnant (including health care providers) should wear gloves if they need to touch or handle ABITIG.

If you are a woman who could become pregnant you should use effective contraception during treatment with SUNMATIN and for 6 months after the last dose. If you are a male patient and your female partner could become pregnant, you should use effective contraception during treatment with SUNMATIN and for 3 months after the last dose.

**Driving and using machines:**

ABITIG may affect your ability to drive a vehicle and use machines. You should not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how ABITIG affects you.

**ABITIG contains lactose and sodium:**

ABITIG contains lactose (which is 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 ABITIG.

ABITIG also contains sodium (4,6 mg sodium per tablet - 18,4 mg sodium per daily dose). To be taken into consideration by patients on a controlled sodium diet.

**3. How to take ABITIG**

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

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

Your doctor will tell you how long your treatment with ABITIG will last. Do not stop your treatment without discussing it with your doctor first.

If you have the impression that the effect of ABITIG is too strong or too weak, tell your doctor or pharmacist.

The usual dose is 4 tablets once a day.

**Do not take ABITIG with food.**

Take ABITIG at least one hour before or at least two hours after eating. Swallow the tablets whole with water. Do not break the tablets.

ABITIG is taken with a medicine called prednisone or prednisolone.

Take the prednisone or prednisolone exactly as your doctor has instructed you. You have to take prednisone or prednisolone every day you take ABITIG.

**If you take more ABITIG than you should:**

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton and this leaflet, so that the hospital staff can easily tell what you have taken.

**If you forget to take ABITIG:**

If you have missed your dose of ABITIG and/or prednisone or prednisolone by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take ABITIG and/or prednisone or prednisolone at the next regularly scheduled time.

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

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

**If you stop taking ABITIG:**

Do not stop taking ABITIG and/or prednisone or prednisolone unless your doctor tells you to.

**4. Possible side effects**

ABITIG can have side effects.

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

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

- swelling of your 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 ABITIG. 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:**

***Frequent side effects:***

- heart failure (shortness of breath, fatigue and weakness, swelling in your legs, ankles and feet, persistent cough or wheezing with white or pink blood-tinged phlegm), congestive heart failure (a chronic progressive condition in which fluid builds up within the heart and causes it not to pump efficiently), left ventricular diastolic dysfunction and decreased left ventricular ejection fraction (shortness of breath or feeling of exertion while at rest, chest pain or extreme tiredness)
- angina pectoris (a pain or uncomfortable feeling in your chest, often spreading to your arms or neck and sometimes to your shoulders and back)
- changes in the way your heart beats (beating faster or irregular)
- abnormal heart rhythm (a fluttering in the chest, chest pain, fast or slow heart beat, fainting or dizziness)
- severe infection called sepsis (fever and chills, nausea, vomiting, diarrhoea)
- too low levels of potassium in your blood (abnormal or slow heart rate, low blood pressure, cramps, weakness)
- Disease of the liver, failure of the liver to function (also called acute liver failure) which may cause yellowing of your skin and whites of the eyes (jaundice), nausea, vomiting and a general sense of feeling unwell
- high triglyceride levels in your blood (yellowish deposits of fat on or around your eyelids)
- blood in your urine

***Less frequent side effects:***

- adrenal insufficiency (pain in your muscles and joints, low blood pressure making you dizzy when standing up, cravings for salt)
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- rhabdomyolysis (rapid breakdown of muscle tissue causing unexplained muscle pain, tenderness or weakness)
- inflammation of your lungs (difficulty breathing, wheezing, dry cough)

***Frequency unknown side effects:***

- heart attack (pain in your chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath)
- changes in the electrical activity of your heartbeat as measured by an electrocardiogram (ECG)
- The death of cells in the liver and where the liver is scarred and permanently damaged

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 (strong and frequent urge to urinate, pain and burning sensation when urinating, cloudy, bloody or strong-smelling urine, abdominal pain, nausea and vomiting)
- high blood pressure
- diarrhoea, indigestion
- increased liver enzymes (alanine aminotransferase or aspartate aminotransferase) when your blood is tested
- bone fractures

***Less frequent side effects:***

- weak muscles

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 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 ABITIG.

**5. How to store ABITIG**

- Store at or below 30 °C.
- Protect from light.
- Keep in the original bottle until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Women of child-bearing age, pregnant women or those who may potentially be pregnant (including health care providers) must use protection (e.g. gloves) when handling ABITIG.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

**6. Contents of the pack and other information****What ABITIG contains:**

The active substance in ABITIG is abiraterone acetate.

Each tablet contains 250 mg abiraterone acetate.

The other ingredients are:

Butylated hydroxyanisole

Croscarmellose sodium

Hypromellose

Lactose monohydrate

Magnesium stearate

Microcrystalline cellulose

Sodium laurilsulfate

**What ABITIG looks like and contents of the pack:**

White to off-white, oval, biconvex, uncoated tablet debossed with “993” on one side and plain on the other side.

White, round, high density polyethylene bottle with a white, polypropylene cap.

Pack size: 120 tablets.

**Holder of certificate of registration:**

Ranbaxy Pharmaceuticals (Pty) Ltd - Roodepoort

14 Lautre Road

Stormill, Ext.1, Roodepoort

Johannesburg 1724

011 495 0100

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