Applicant : Eurolab (Pty) Ltd
Proprietary name : Abizista 250 mg & 500 mg
Dosage form and strength : Film-coated tablets
Date of submission : 20 November 2023
Approval date : 29 February 2024

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

ABIZISTA 250 mg, 250 mg, Film-coated tablets

ABIZISTA 500 mg, 500 mg, Film-coated tablets

Abiraterone Acetate

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking ABIZISTA.

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

1. WHAT IS ABIZISTA AND WHAT IT IS USED FOR

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

When ABIZISTA 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 this medicine, 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 ABIZISTA

Do not take ABIZISTA:

- if you are hypersensitive (allergic) to abiraterone acetate or any of the other ingredients of ABIZISTA (listed in section 6).
- if you are a woman, especially if pregnant or breastfeeding. ABIZISTA is for use in male patients only.
- if you have been diagnosed with severe liver disease.
- In combination with rifampicin (TB medicine).
- With prednisone or prednisolone (medicine to help with side effects) in combination with Ra-223 (a medicine used to treat prostate cancer that has spread to the bone and is causing symptoms but has not spread to other organs).

Warnings and precautions

Special care should be taken with ABIZISTA. Talk to your doctor or pharmacist before taking ABIZISTA:

- if you have been diagnosed with 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 or are being treated with medicines for these conditions.
- if you have an irregular or rapid heart rate or are being treated with medicines for these conditions.
- if you have swelling in the feet, ankles, or legs.
- if you have been diagnosed with liver disease. 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.
- about the need to take this medicine with prednisone or prednisolone.
- about possible effects on your bones.
- if you have taken a medicine known as ketoconazole in the past for prostate cancer.
- if you have high or low blood sugar.
- about the need to take this medicine with any other chemotherapy.
- about the occurrence of decrease in red blood cells, reduced sex drive (libido), muscle weakness and/or muscle pain.
- if you take Ra-223 following treatment with ABIZISTA and prednisone/prednisolone, you must wait 5 days before starting treatment with Ra-223. ABIZISTA must not be given in combination with Ra-223 due to a possible increase in the risk of bone fracture or death.

Children and adolescents

This medicine is not for use in children and adolescents.

Other medicines and ABIZISTA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary

or traditional medicines.)

Some medicines may affect how ABIZISTA works or make it more likely that you will have side effects.

ABIZISTA can also affect how some other medicines work. These include:

- rifampicin, rifabutin, rifapentine (used to treat infection)
- phenytoin, carbamazepine, phenobarbitone (used to treat epilepsy)
- dextromethorphan (included in certain cough mixtures or cold and flu medication)
- paroxetine, haloperidol (used in the treatment of certain psychiatric conditions)
- propafenone, flecainide (used to treat arrhythmia/irregular heartbeat)
- pioglitazone (used to treat diabetes)
- spironolactone (“water pill” used to treat fluid build-up due to heart failure, liver, or kidney disease)

Tell your doctor or pharmacist if you take any of these.

ABIZISTA with food, drink, and alcohol

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

Pregnancy and breastfeeding

Pregnancy, breastfeeding and fertility

ABIZISTA is not for use in women. The effect of ABIZISTA during pregnancy is not known. ABIZISTA may cause harm to the unborn child if it is taken by women who are pregnant. Women who are pregnant or who may be pregnant should wear gloves if they need to touch or handle ABIZISTA. Use of reliable method of contraception is required.

Driving and using machines

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

ABIZISTA contains lactose and sodium

ABIZISTA 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 ABIZISTA. This medicine also contains sodium and therefore this should be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE ABIZISTA

Do not share medicines prescribed for you with any other person.
Always take ABIZISTA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is ABIZISTA is 1 g (two tablets of 500 mg or four tablets of 250 mg) taken once a day.

Taking this medicine:

- Take this medicine by mouth.
- Do not take ABIZISTA with food.
- Take ABIZISTA at least one hour before or at least two hours after eating (see section 2, “ABIZISTA with food, drink, and alcohol”).
- ABIZISTA is taken with a medicine called prednisone or prednisolone. Take the prednisone or prednisolone exactly as your doctor has told you.
- Swallow the tablets whole with water. Do not break the tablets.
- Your doctor will monitor your blood pressure and blood tests regularly.

If you take more ABIZISTA 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 ABIZISTA

If you forget to take ABIZISTA or prednisone or prednisolone, take your usual dose the following day. If you forget to take ABIZISTA or prednisone or prednisolone for more than one day, talk to your doctor without delay.

If you stop taking ABIZISTA

Do not stop ABIZISTA without advice. Take ABIZISTA for as long as your doctor recommends.

4. POSSIBLE SIDE EFFECTS

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

If any of the following happens, stop taking ABIZISTA and 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to ABIZISTA. 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:

- Muscle weakness, muscle twitches or a pounding heartbeat (palpitations). These may be signs that the level of potassium in your blood is low.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- urinary tract infection
- severe infections (called sepsis)
- low blood potassium (seen on blood test)
- high fat levels in your blood (seen on blood test)
- heart failure
- chest pain (called angina pectoris)
- irregular heartbeat (called atrial fibrillation)
- rapid heart rate (called tachycardia)
- high blood pressure
- loose stools
- indigestion (dyspepsia)
- liver function enzyme increases (seen in blood tests)
- rash
- bone fractures
- blood in urine
- fluid retention (swelling) in your legs or feet.

Less frequent side effects:

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

- heart muscle takes longer than normal to recharge between beats, seen as changes in electrocardiogram (QT prolongation)
- lung irritation (also called allergic alveolitis)
- liver disease (fulminant hepatitis)
- failure of the liver to function (also called acute liver failure).
- muscle weakness and/or muscle pain

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 ABIZISTA.

5. HOW TO STORE ABIZISTA

Store at or below 25 °C.

Store all medicines out of reach of children.

Store in the original package / container.

Do not use this medicine after the expiry date which is stated on the packaging after "EXP". The expiry date refers to the last day of the month.

Return all unused medicine to your pharmacist.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ABIZISTA contains:

The active substance is Abiraterone acetate.

The other ingredients are Croscarmellose sodium, Type A Sodium laurilsulfate, Povidone K 30 (E1201), Cellulose Microcrystalline 102 (E460), Lactose monohydrate, Silica Colloidal anhydrous (E551), Magnesium stearate (E470b), Water, purified, Poly(vinyl alcohol) (E1203), Titanium dioxide (E171), Macrogol 3350 (E1521), Talc (E553b), Iron oxide red (E172) or Iron oxide black (E172).

What ABIZISTA looks like and contents of the pack

ABIZISTA 250 mg:

White to off-white, oval-shaped film-coated tablets, debossed with “250” on one side.

AluminiumOPA/Alu/PVC blisters or Aluminium-PVC/PE/PVDC blisters of 120 tablets.

ABIZISTA 500 mg:

Purple, oval-shaped film-coated tablets, debossed with “500” on one side.

AluminiumOPA/Alu/PVC blisters or Aluminium-PVC/PE/PVDC blisters of 60 tablets.

Holder of Certificate of Registration

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