

Xbira 250mg[®] Tablets

Consumer Medication Information Leaflet (RiMUP)

Abiraterone Acetate USP (250 mg)

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What XBIRA 250 is used for

XBIRA 250 is indicated with prednisone or prednisolone for the treatment of prostate cancer that has spread to other parts of the body.

How XBIRA 250 works

XBIRA 250 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. XBIRA 250 stops your body from making testosterone; this can slow the growth of prostate cancer

Before you use XBIRA 250

When you must not use it

Do not take XBIRA 250

- if you are allergic to abiraterone acetate or any of the other ingredients of this medicine (listed in section 8).
- if you are a woman, especially if pregnant. XBIRA 250 is for use in male patients only.

Children and adolescents

- This medicine is not for use in children and adolescents. If XBIRA 250 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.

Before you start to use it

XBIRA 250 can make high blood pressure or heart failure or low blood potassium worse. Taking prednisone or prednisolone with XBIRA 250 helps to avoid worsening of these conditions. If you have these conditions, or other heart or blood vessel problems, discuss them with your doctor. Your blood pressure, serum potassium and signs and symptoms of fluid retention will be monitored clinically at least monthly.

If you are having sex with a pregnant woman you need to use a condom. If you are having sex with a woman who can become pregnant you need to use a condom and another effective birth control method.

XBIRA 250 may affect your liver. Rarely, failure of liver to function (called 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. When you are taking XBIRA 250, your doctor will check your blood to look for any effects of XBIRA 250 on your liver.

XBIRA 250 may decrease bone density. Talk to your doctor if you have bone problems.

XBIRA 250 contains lactose. You should not take XBIRA 250 if you have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because XBIRA 250 may increase the effects of a number of medicines including some medicines for diabetes, heart medicines, tranquilisers, herbal medicines

(e.g., St John's wort) and others. Your doctor may want to change the dose of these medicines. Also, some medicines may increase or decrease the effects of XBIRA 250. This may lead to side effects or to XBIRA 250 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 medicine

- used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol);
- 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)].

Tell your doctor if you are taking any of the medicines listed above.

How to use Xbira 250

How much to take

The recommended dose is 1,000 mg (four 250 mg tablets) once a day.

XBIRA 250 should be swallowed whole with water. Do not break the tablets.

When to take it

Take XBIRA 250 at least two hours after eating and do not eat anything for at least one hour after taking XBIRA 250

Taking XBIRA 250 with food may cause side effects.

How long to take it

Do not stop any treatment unless your doctor tells you to do so.

If you forget to take it

- If you forget to take XBIRA 250 or prednisone or prednisolone, take your usual dose the following day.

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- If you forget to take XBIRA 250 or prednisone or prednisolone for more than one day, talk to your doctor without delay.

If you take too much (overdose)

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

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

Special instruction for preparation or administration:

Women who are pregnant or women who may be pregnant should not handle XBIRA 250 without protection, for example, gloves.

While you are using Xbira 250

Things you must do

- Be sure to keep all your doctor's appointments so your progress can be checked. Your doctor will want to some blood and other tests from time to time to check on your progress.
- Be sure to follow your doctor's instructions about other medicines you should take, and other things you should do.
- Tell any other doctors and pharmacists who are treating you that you are taking XBIRA 250.
- If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking XBIRA 250.
- If you have any further questions on the use of this product, ask your doctor.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give XBIRA 250 to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

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

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking XBIRA 250 and see a doctor immediately if you notice any of the following:

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

The most common side effects include swollen hands, ankles or feet, low level of potassium in the blood, urinary tract infection and high blood pressure. Other side effects include high fat levels in your blood, liver function test increases, indigestion, blood in urine, chest pain, heart beat disorders, heart failure, rapid or irregular heart rate associated with feeling faint or lightheaded, and adrenal gland problems.

Other side effects reported were lung irritation (called allergic alveolitis), breakdown of muscle tissue (called rhabdomyolysis), muscle weakness and / or muscle pain (called myopathy), and failure of liver to function (called acute liver failure).

If these or any other effects occur, talk to your doctor without delay.

Reporting of side effects

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <http://npra.moh.gov.my> (Consumer -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of Xbira 250

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton, cardboard wallet, and the blister. The expiry date refers to the last day of that month.

Storage

Store below 30°C. Protect from light

Disposal

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description

What it looks like?

Description:

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

Ingredients

Inactive Ingredients

Microcrystalline cellulose, lactose monohydrate, povidone, sodium lauryl sulfate, croscarmellose sodium, purified water, colloidal silicon dioxide, magnesium stearate

MAL Number

MAL20076027AZ

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Manufacturer

Aizant Drug Research Solutions Private
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Sy No. 172 & 173, Apparel Park Road,
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Product Registration Holder

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Date of Revision

15/02/2021

Serial Number

NPRA (R2) 19/119