XBIRA 500 MG (ABIRATERONE ACETATE FILM-COATED TABLETS USP 500 MG)

Abiraterone Acetate USP (500 mg)

What is in this leaflet

What XBIRA is used for

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

How XBIRA works

XBIRA stops your body from making testosterone. Research has shown that testosterone helps to fuel the tumor. Reducing the production of testosterone is important to manage your illness.

Before you use XBIRA

-When you must not use it

Pregnancy and lactation
XBIRA must not be taken by women who are pregnant or breast-feeding or might be pregnant since XBIRA may affect the baby.

Women, infants and children
XBIRA is not for use in women and children.

Kidney disease
XBIRA may be used in patients with kidney disease.

Liver disease
You should not take XBIRA if you have severe liver disease. Your doctor will decide whether XBIRA can be used if you have mild or moderate liver problems.

-Before you start to use it

XBIRA can make high blood pressure or heart failure or low blood potassium worse. Taking prednisone or prednisolone with XBIRA helps to avoid worsening of these conditions. If you have these conditions, or other heart or blood vessel problems, discuss them with your doctor. QT prolongation and *Torsades de Pointes* have been observed in patients who develop hypokalemia while taking XBIRA. 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 may affect your liver. Rarely, failure of the 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 your doctor will check your blood to look for any effects of XBIRA on your liver.

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

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

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

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

To reduce the chance of developing high blood pressure or heart effects or low blood potassium, your doctor will prescribe either prednisone or prednisolone. You need to take one of these drugs daily while you are taking XBIRA. Do not stop taking prednisone or prednisolone unless your doctor tells you to do this. During a medical emergency, the dose of prednisone or prednisolone may need to be increased. Your doctor will look at your situation and tell you whether this is necessary.

Your doctor may prescribe other treatments to be continued while you are taking XBIRA and prednisone or prednisolone.

Taking XBIRA with certain other medicines/treatments may result in greater or lesser effects or even side effects from these medicines/treatments. Tell your doctor about everything you are taking or being treated with so that your doctor can tell you whether you can continue the medicines / treatments you are taking or reduce the dose, etc.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because XBIRA may increase the effects of a number of medicines including some medicines for diabetes. Your doctor may want to change the dose of these medicines.

How to use XBIRA

-How much to use

The usual daily dose of XBIRA is 1000 mg (two 500 mg tablets) taken as a single dose.

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XBIRA is prescribed with prednisone or prednisolone. The usual dose of prednisone or prednisolone is 5 or 10 mg daily taken according to your doctor's instructions.

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

-When to use it

Do not take XBIRA with food. Take XBIRA as a single dose once daily on an empty stomach. XBIRA must be taken at least two hours after eating and food must not be eaten for at least one hour after taking XBIRA.

Taking XBIRA with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.

-How long to use it

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

-If you forget to use it

If you miss a daily dose of XBIRA or prednisone or prednisolone, take your normal dose the following day. If more than one daily dose is missed, talk to your doctor.

-If you use too much (overdose)

If you accidentally take more than the usual dose, contact your doctor or pharmacist.

While you are using XBIRA

-Things you must do

Be sure to keep all your doctor's appointments so your progress can be checked. Your doctor will want to do some blood and other tests from time to time to check on your progress.

Be sure to follow up 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. If you are undergoing anesthesia, tell your anesthetist that you are taking XBIRA.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking XBIRA. 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 to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machinery
It is thought that XBIRA will not affect your ability to drive or use any tools or machines.

Side effects

Stop taking XBIRA and see a doctor immediately if you notice signs of low blood potassium: muscle weakness, muscle twitches, fast or uneven heartbeats.

The most common side effects of XBIRA are fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures. Other side effects from XBIRA are 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 were lung irritation (called allergic alveolitis), breakdown of muscle tissue (called rhabdomyolysis), muscle weakness and/or muscle pain (called myopathy), failure of the liver to function (called acute liver failure), and anaphylactic reaction (severe allergic reactions that include, but are not limited to difficulty swallowing or breathing, swollen face, lips, tongue or throat, or an itchy rash (urticaria)).

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

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of XBIRA

-Storage

Store XBIRA tablets below 30°C. Keep XBIRA out of the reach of children.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Purple colored, oval shaped, biconvex bevel edge film coated tablet, debossed with "A" on one side and "500" on other side.

XBIRA 500 MG (ABIRATERONE ACETATE FILM-COATED TABLETS USP 500 MG)

Abiraterone Acetate USP (500 mg)

-Ingredients

- Active ingredient(s)
  Abiraterone acetate

- Inactive ingredient(s)
  Tablet core: lactose monohydrate, croscarmellose sodium, Hypromellose, sodium lauryl sulfate, colloidal

  silicon dioxide, silicified microcrystalline cellulose and magnesium stearate.

  Tablet film-coat: (Opadry II Purple 85F500067): polyvinyl alcohol, titanium dioxide, macrogol / PEG, talc, iron oxide red, ferrosoferric oxide/black iron oxide.

-MAL number

MALXXXXXXXAZ

Manufacturer

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Product Registration Holder

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