

ARABITRO[®] 250mg Tablets

Abiraterone Acetate Tablets USP 250mg

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What ARABITRO is used for

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

How ARABITRO works

ARABITRO 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 ARABITRO

- When you must not use it

Pregnancy and lactation

ARABITRO must not be taken by women who are pregnant or breast-feeding or might be pregnant since ARABITRO may affect the baby. If you are pregnant or might be pregnant, wear gloves if you need to touch or handle ARABITRO. *Women, infants and children* ARABITRO is not for use in women and children.

- Before you start to use it

ARABITRO can make high blood pressure or heart failure or low blood potassium worse. Taking prednisone or prednisolone with ARABITRO helps to avoid worsening of these conditions. If you have these conditions, or other heart or blood vessel problems, discuss them with your doctor.

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.

ARABITRO 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 ARABITRO your doctor will check your blood to look for any effects of ARABITRO on your liver. ARABITRO may decrease bone density. Talk to your doctor if you have bone problems.

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

ARABITRO contains more than 1mmol (or 25.04mg) sodium per dose of 4 tablets. Talk to your doctor if you are on a controlled sodium diet.

- Taking other medicines

To reduce the chance of developing high blood pressure or heart failure 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 ARABITRO. 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 ARABITRO and prednisone or prednisolone. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because ARABITRO 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 ARABITRO

- How much to use

The usual daily dose of ARABITRO is 1000mg (four tablets) taken as a single dose.

ARABITRO 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.

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

- When to use it

Do not take ARABITRO with food. ARABITRO should be taken at least two hours after eating and no food should be eaten for at least one hour after taking ARABITRO. Taking ARABITRO 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 ARABITRO 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.

Special instruction for preparation or administration:

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

While you are using it

- 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

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you should take, and other things you should do.

Tell any other doctors and pharmacists who are treating you that you are taking ARABITRO. If you are undergoing anesthesia, tell your anesthetist that you are taking ARABITRO.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking ARABITRO.

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 ARABITRO to anyone else, even if they have the same symptoms or condition as you

- Things to be careful of

Driving and using machines

It is thought that ARABITRO will not affect your ability to drive or use any tools or machines

Side effects

Stop taking ARABITRO 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 ARABITRO are swollen hands, ankles or feet, low level of potassium in the blood, urinary tract infection and high blood pressure. Other side effects from ARABITRO are high fat levels in your blood, liver function test increases, indigestion, blood in urine, chest pain, heart beat disorders, heart failure, rapid heart rate 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 the liver to function (called acute liver failure).

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

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

Storage and Disposal of ARABITRO

- Storage

Store ARABITRO tablets below 30°C.

Keep ARABITRO out of the reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

ARABITRO tablets are white to off white oval shapes uncoated tablets, debossed with “G” on one side and 135 on other side.

- Ingredients

- Active ingredient
Abiraterone acetate

- Inactive ingredients
Lactose monohydrate,
Microcrystalline cellulose,
Croscarmellose sodium,
Colloidal silicon dioxide,
Magnesium stearate,
Povidone K-30, and Sodium lauryl sulfate.

- MAL number:

MAL20126019AZ

Manufacturer

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Aurangabad 431154 Maharashtra
State, INDIA

Product Registration Holder

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- 18/04/2022

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