

ABYTONE TABLETS

Abiraterone Acetate Tablet (250 mg)

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What ABYTONE is used for

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

How ABYTONE works

ABYTONE stops your body from making testosterone; this can slow the growth of prostate cancer. Research has shown that testosterone helps to fuel the tumor.

Reducing the production of testosterone is important to manage your illness.

When ABYTONE 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 mineral known as potassium in your blood.

Before you use ABYTONE

- When you must not use it
- Do not take this medicine if you have an allergy to:
 - abiraterone acetate
 - any of the other ingredients listed at the end of this leaflet
- Pregnancy and lactation
Pregnancy and lactation
ABYTONE must not be taken by women who are pregnant or breastfeeding or might be pregnant since ABYTONE may affect the baby. If you are pregnant or might be pregnant, wear gloves if you

need to touch or handle ABYTONE. Women, infants and children ABYTONE is not for use in women and children.

- Do not take this medicine if you have severe liver damage
- Do not take this medicine in combination with Ra-223 (which is used to treat prostate cancer).
- Before you start use it
ABYTONE can make high blood pressure or heart failure or low blood potassium worse. Taking prednisone or prednisolone with ABYTONE 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.

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

ABYTONE contains lactose. You should not take ABYTONE if you have galactose intolerance, Lapp lactase deficiency or glucosgalactose malabsorption. ABYTONE 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 ABYTONE. 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 ABYTONE and prednisone or prednisolone. Taking ABYTONE with certain other medicines may result in greater or lesser effects or even side effects from these medicines. Tell your doctor about everything you are taking so that your doctor can tell you whether you can continue the medicines you are taking or reduce the dose, etc.

If you have diabetes, your blood sugar may drop if you take ABYTONE plus prednisone/prednisolone with some medicines for diabetes such as pioglitazone or repaglinide. Tell your healthcare provider if you monitor your blood sugar while taking a medicine for diabetes and notice a drop in your blood sugar.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because ABYTONE 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 ABYTONE

- How much to use
The usual daily dose of ABYTONE is 1000mg (four tablets) taken as a single dose.

ABYTONE 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.

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

- When to use it
Do not take ABYTONE with food. ABYTONE should be taken at least two hours after eating and no food should be eaten for at least one hour

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after taking ABYTONE.

Taking ABYTONE 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 ABYTONE 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 ABYTONE 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 you should take, and other things you should do.

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

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

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 ABYTONE 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 ABYTONE will not affect your ability to drive or use any tools or machines

Side effects

Stop taking ABYTONE 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 ABYTONE are swollen hands, ankles or feet, low level of potassium in the blood, urinary tract infection and high blood pressure. Other side effects from ABYTONE 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 reported 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 reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers □ Reporting side effects to medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of ABYTONE

- Storage

Store below 30° C. Protect from light.

Keep ABYTONE 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

ABYTONE tablets are white to off-white, oval-shaped tablets debossed with A on one side and 250 on other side.

- Ingredients

- Active ingredient
Abiraterone acetate

Inactive ingredients

Inter-granular Portion

Microcrystalline Cellulose
Lactose Monohydrate
Povidone
Sodium Lauryl Sulfate
Croscarmellose Sodium (Part-1)
Purified water

Extra-granular Portion

Croscarmellose Sodium (Part-2)
Microcrystalline Cellulose (Part-2)
Colloidal Silicon Dioxide
Magnesium Stearate

- MAL number:

MAL22056055ACZ

Manufacturer

Aizant Drug Research
Solutions (P) Ltd.,
Sy. No.172&173, Apparel
Park Road, Dulapally
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Product registration holder

Accord Healthcare Sdn. Bhd.
Suite 12a-15, Level 12a, Wisma Zelan
No 1 Jalan Tasik Permaisuri 2,
Bandar Tun Razak,
56000 Kuala Lumpur

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