

ABRONE FILM COATED TABLETS

Abiraterone Acetate (250mg, 500mg)

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What Abrone is used for

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

How Abrone works

Abrone 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 Abrone

- When you must not use it

Pregnancy and lactation

Abrone must not be taken by women who are pregnant or breast-feeding or might be pregnant since Abrone may affect the baby. If you are pregnant or might be pregnant, wear gloves if you need to touch or handle Abrone tablets if broken, crushed, or damaged.

Women, infants and children

Abrone is not for use in women and children.

Kidney disease

Abrone may be used in patients with kidney disease.

Liver disease

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

- Before you start to use it

Abrone can make high blood pressure or heart failure or low blood potassium worse. Taking prednisone or prednisolone with Abrone 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 Abrone. 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.

Abrone 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 Abrone your doctor will check your blood to look for any effects of Abrone on your liver.

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

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

This medicine contains less than 1 mmol sodium (23 mg) per dosage units, that is to say essentially 'sodium free'.

- 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 Abrone. 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 Abrone and prednisone or prednisolone.

Taking Abrone 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 Abrone 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 Abrone

- How much to use

The usual daily dose of Abrone is 1000mg (two 500 mg tablets or four 250 mg tablets) taken as a single dose.

Abrone 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.

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

- When to use it

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

Taking Abrone 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 Abrone or

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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 Abrone

- *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 Abrone. If you are undergoing anesthesia, tell your anesthetist that you are taking Abrone.

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

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

Side effects

Stop taking Abrone 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 Abrone are fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures. Other side effects from Abrone 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 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 Abrone

Storage

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not take this medicine after the expiry date, which is stated on the pack.

Disposal

If you have any unwanted capsules do not put them in wastewater or household rubbish. Ask your pharmacist how to dispose of tablets you do not need.

This will help to protect the environment.

Product Description

What it looks like

Abrone 250 mg Film Coated Tablets - Purple, oval-shaped, film-coated tablets, debossed with "A" on one side and "250" on other side.

Abrone 500 mg Film Coated Tablets - Purple, oval-shaped, film-coated tablets, debossed with "A" on one side and "500" on other side.

Ingredients

- Active ingredients
The active substance of Abrone 250 mg Film Coated Tablets is 250 mg Abiraterone Acetate.
The active substance of Abrone 500 mg Film Coated Tablets is 500 mg Abiraterone Acetate.

- Inactive ingredients

Tablet core:

- Lactose Monohydrate
- Croscarmellose Sodium
- Hypromellose
- Sodium Lauryl Sulfate
- Silicified Microcrystalline Cellulose
- Colloidal Silicon Dioxide
- Magnesium Stearate

Film coat:

Abrone 250 mg Film Coated Tablets dan Abrone 500 mg Film Coated Tablets: Opadry II Complete Film Coating System 85F90093 Purple

MAL number(s):

Abrone 250 mg Film Coated Tablets: MALXXXXXXXXX
Abrone 500 mg Film Coated Tablets: MALXXXXXXXXX

Manufacturer

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Product Registration Holder

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