

ESTATIGA 500mg Film-Coated Tablets

Abiraterone Acetate 500mg

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What Estatiga are used for

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

How Estatiga Work

It 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 Estatiga

When you must not take it

Pregnancy and lactation

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

If you are pregnant or might be pregnant, wear gloves if you need to touch or handle Estatiga.

Women, infants and children

Estatiga is not for use in women and children.

Kidney disease

Estatiga may be used in patients with kidney disease.

Liver disease

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

Before you start to use it

Estatiga can make high blood pressure or heart failure or low blood potassium worse. Taking prednisone or prednisolone with Estatiga helps to avoid worsening of 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 Estatiga. 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.

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

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

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

Estatiga contains less than 1 mmol (or 23mg) per tablet, 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 Estatiga. 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 Estatiga and prednisone or prednisolone.

Taking Estatiga 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 Estatiga 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 Estatiga

How much to use

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

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

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

When to use it

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

Taking Estatiga 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 Estatiga 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.

Special instruction for preparation or administration:

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

While you are using Estatiga

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 Estatiga. If you are undergoing anesthesia, tell your anesthetist that you are taking Estatiga.

If you are about start on any new medicines, tell your doctor or pharmacist that you are taking Estatiga.

If you have 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 Estatiga 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 Estatiga will not affect your ability to drive or use any tools or machines.

Side Effects

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

Storage

Store below 30°C. Protect from light and moisture.

Keep out of reach and sight of children.

Disposal

Medicine 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

Purple to brown film coated tablets, oblong 20x10 mm

Ingredients

Active ingredient
Abiraterone acetate 500mg

Inactive ingredient
Lactose monohydrate,
Croscarmellose sodium,
Hypromellose, Sodium laurilsulfate,
purified water, Silicified
microcrystalline cellulose, Silica
colloidal anhydrous,

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Magnesium Stearate, Opadry II
85F200050 – Purple, (Polyvinyl
alcohol, Macrogol, Talc, Titanium
Dioxide, Ferric Oxide red, Ferric
Oxide black)

MAL Number

XXXXX

Manufacturer

Delpharm Lille SAS
Parc D Activites Roubaix Est22 Rue
De Toufflers Cs 50070,
Lys Lez Lannoy Cedex, 59452,
France.

Product Registration Holder

Wellesta Healthcare Sdn. Bhd.
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