



TLPH

Information for the patient

Abyrone 250 mg tablets

abiraterone acetate

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

What Abyrone is and what it is used for

What you need to know before you take Abyrone

How to take Abyrone

Possible side effects

How to store Abyrone

Contents of the pack and other information

1. What Abyrone is and what it is used for

Abyrone contains a medicine called abiraterone acetate. Abyrone stops your body from making estosterone; this can slow the growth of prostate cancer. It is used to treat prostate cancer in adult men that has spread to other parts of the body.

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 chemical known as potassium in your blood.

2. What you need to know before you take Abyrone

Do not take Abyrone

if you are allergic to abiraterone acetate or any of the other ingredients of this medicine (listed in section 6).

if you are or may potentially be pregnant. Abyrone is not for use in women.

if you have severe liver damage.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

if you have liver problems

if you have had high blood pressure or heart failure or low blood potassium (low blood potassium may increase the risk of heart rhythm problems)

if you have had other heart or blood vessel problems

if you have an irregular or rapid heart rate

if you have shortness of breath

if you have gained weight rapidly

if you have swelling in the feet, ankles, or legs

if you have taken a medicine known as ketoconazole in the past for prostate cancer

about the need to take this medicine with prednisone or prednisolone

about possible effects on your bones

if you have high blood sugar.

Tell your doctor if you have any of the following:

Any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Blood monitoring

Abyrone may affect your liver, and you may not have any symptoms. When you are taking this medicine, your doctor will check your blood to look for any effects on your liver.

Other medicines and Abyrone

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because Abyrone may increase the effects of a number of medicines including heart medicines, tranquilizers, herbal medicines (e.g., St John's wort) and others. Your doctor may want to change the dose of these medicines. Also, some medicines may increase or decrease the effects of Abyrone. This may lead to side effects or to Abyrone not working as well as it should.

Other medicines taken with Abyrone

Androgen deprivation treatment may increase the risk of heart rhythm problems. Tell your doctor if you are receiving medicinal products

used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol);

known to increase the risk of heart rhythm problems [e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics (used for serious mental illnesses)].

Abyrone with food

This medicine must not be taken with food (see section 3, "Taking this medicine").

Taking Abyrone with food may cause side effects.

Pregnancy and breast-feeding

Abyrone is not for use in women.

This medicine may cause harm to the unborn child if it is taken by women who are pregnant, and should not be taken by women who are breast-feeding an infant.

Women who are pregnant or who may be pregnant should wear gloves if they need to touch or handle Abyrone.

If you are having sex with a woman who can become pregnant, use a condom and another effective birth control method. If you are having sex with a pregnant woman, use a condom to protect the unborn child.

Driving and using machines

This medicine is not likely to affect your being able to drive or use any tools or machines.

Abyrone contains lactose and sodium

Abyrone contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine also contains approximately 27 mg of sodium in a four tablet daily dose. To be taken into consideration by patients on a controlled sodium diet.

Decrease in red blood cells, reduced sex drive, muscle weakness and/or muscle pain may occur.

3. How to take Abyrone

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended dose is 1,000 mg, (four tablets) once a day.

Taking this medicine

Take this medicine by mouth.

Do not take Abyrone with food.

Take Abyrone at least two hours after eating and do not eat anything for at least one hour after taking Abyrone (see section 2, "Abyrone with food").

Swallow the tablets whole with water.

Do not break the tablets.

Abyrone is taken with a medicine called prednisone or prednisolone. Take the prednisone or prednisolone exactly as your doctor has told you.

You need to take prednisone or prednisolone every day while you are taking Abyrone.

The amount of prednisone or prednisolone you take may need to change if you have a medical emergency. Your doctor will tell you if you need to change the amount of prednisone or prednisolone you take. Do not stop taking prednisone or prednisolone unless your doctor tells you to.

Your doctor may also prescribe other medicines while you are taking Abyrone and prednisone or prednisolone.

Use in children

This medicine is not for use in children and adolescents.

If you take more Abyrone than you should

If you take more than you should, talk to your doctor or go to a hospital immediately.

If you forget to take Abyrone

If you forget to take Abyrone or prednisone or prednisolone, take your usual dose the following day.

If you forget to take Abyrone or prednisone or prednisolone for more than one day, talk to your doctor without delay.

If you stop taking Abyrone

Do not stop taking Abyrone or prednisone or prednisolone unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Abyrone and see a doctor immediately if you notice any of the following:

- Muscle weakness, muscle twitches or a pounding heart beat (palpitations). These may be signs that the level of potassium in your blood is low.

Other side effects include:

Very common (may affect more than 1 in 10 people):

Fluid in your legs or feet, low blood potassium, high blood pressure, urinary tract infection, diarrhoea.

Common (may affect up to 1 in 10 people):

High fat levels in your blood, liver function test increases, chest pain, heart beat disorders, heart failure, rapid heart rate, severe infections called sepsis, bone fractures, indigestion, blood in urine, rash.

Uncommon (may affect up to 1 in 100 people):

Adrenal gland problems (related to salt and water problems), muscle weakness and/or muscle pain.

Rare (may affect up to 1 in 1,000 people):

Lung irritation (also called allergic alveolitis).

Not known (frequency cannot be estimated from the available data):

Heart attack, changes in ECG - electrocardiogram (QT prolongation).

Bone loss may occur in men treated for prostate cancer. Abyrone in combination with prednisone or prednisolone may increase bone loss.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Abyrone

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle-label.

The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help to protect the environment.

6. Contents of the pack and other information

What Abyrone contains

The active substance is abiraterone acetate. Each tablet contains 250 mg abiraterone acetate.

The other ingredients are cellulose, microcrystalline croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone, silica, colloidal anhydrous, and sodium laurilsulfate (see section 2, "Abyrone contains lactose and sodium").

What Abyrone looks like and contents of the pack

Abyrone tablets are white to off-white, oval shaped, with "TLPH" written on one side.

The tablets are provided in a plastic bottle. Each bottle contains 120 tablets. Each carton contains one bottle.

Marketing Authorisation Holder

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