
Abiraterone Devatis film coated tablets

abiraterone

Consumer Medicine Information (CMI) summary

What is in this leaflet

This leaflet answers some common questions about Abiraterone Devatis film coated tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Abiraterone Devatis against the benefits this medicine is expected to have for you.

If you have any concerns about being given Abiraterone Devatis ask your doctor.

Keep this leaflet while you are taking Abiraterone Devatis.

You may need to read it again

What Abiraterone Devatis is used for

Abiraterone Devatis is used to treat prostate cancer that has spread to other parts of the body. It reduces the levels of the sex hormone testosterone.

Ask your doctor if you have any questions about why Abiraterone Devatis has been prescribed for you.

This medicine is available only with a doctor's prescription.

Abiraterone Devatis is not addictive.

Before you take Abiraterone Devatis

When you must not use it:

Do not take Abiraterone Devatis:

- if you are allergic (hypersensitive) to abiraterone, or other ingredients of Abiraterone Devatis. See Product Description at the end of this leaflet for a list of ingredients.

Do not take Abiraterone Devatis:

- if the packaging is torn or shows signs of tampering.
- if the expiry date (month and year) printed on the pack has passed. If you take Abiraterone Devatis after the expiry date it may not work.

Do not take Abiraterone Devatis:

- if you are pregnant or maybe potentially pregnant

Abiraterone Devatis is not for use in women and children.

Before you start to use it:

Tell your doctor if you have or have had any medical conditions, especially the following:

Problems with your liver

You should not take Abiraterone Devatis if you have moderate or severe liver disease. Your doctor will decide whether Abiraterone Devatis can be used if you have a mild liver problem.

Abiraterone Devatis may affect your liver. When you are taking Abiraterone Devatis, your doctor will check your blood to look for any effects of Abiraterone Devatis on your liver.

High blood pressure and heart problems

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

Pregnancy

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

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.

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

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 Abiraterone Devatis. 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 Abiraterone Devatis and prednisone or prednisolone.

If you have diabetes, your blood sugar may drop if you take Abiraterone Devatis 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.

Abiraterone Devatis might interact with other medicines/treatments. This may result in greater or lesser effects or even side effects from these medicines/treatments. Tell your doctor if you are taking any other medicines or receiving other treatments, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop. Your doctor can tell you whether you can continue the medicines/treatments you are taking or reduce the dose.

Taking Abiraterone Devatis

How much Abiraterone Devatis to take:

Always take Abiraterone Devatis exactly as your doctor has told you. You must check with your doctor if you are not sure.

The usual daily dose of Abiraterone Devatis is two 500 mg tablets taken as a single dose.

Instructions:

DO NOT TAKE Abiraterone Devatis WITH FOOD

Take Abiraterone Devatis tablets as a single dose once daily on an empty stomach, Abiraterone Devatis must be taken at least two hours after eating and food must not be eaten for at least one hour after taking Abiraterone Devatis.

Taking Abiraterone Devatis with food causes more of this medicine to be absorbed by the body than is needed and this may cause side effects.

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

Abiraterone Devatis 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.

What do I do if I forget to take Abiraterone Devatis?

If you miss a daily dose of Abiraterone Devatis or prednisone or prednisolone, take your normal dose the following day. If more than one daily dose is missed, talk to your doctor.

What do I do if I take too much? (overdose):

If you think you or anybody else has taken too much Abiraterone Devatis, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling 0800 POISON or 0800 764 766.

While you are taking Abiraterone Devatis

Things you must do:

Do not stop taking Abiraterone Devatis unless your doctor tells you to do so.

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.

Ask your doctor or pharmacist if you have any questions.

Tell any other doctors and pharmacists who are treating you that you are taking Abiraterone Devatis. If you are undergoing anaesthesia, tell your anaesthetist that you are taking Abiraterone Devatis.

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

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

Things to be careful of

Driving and using machines

It is thought that Abiraterone Devatis will not affect your ability to drive and use machines.

Side Effects

Like all medicines, Abiraterone Devatis can have side effects. Some of these effects may be serious.

Tell your doctor or pharmacist if you do not feel well while you are being treated with Abiraterone Devatis.

Stop taking Abiraterone Devatis and see a doctor immediately if you notice signs of low blood potassium:

– muscle weakness, muscle twitches, heart palpitations.

The most common side effects of Abiraterone Devatis are diarrhoea, fluid in legs and feet, low blood potassium, urinary tract infection, high blood pressure and bone fractures.

Other side effects from Abiraterone Devatis 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, muscle pains, adrenal gland problems 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.

If you experience any of these side effects and they worry you, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Other side effects not listed above may also occur in some people.

Product Description

Storage

Keep the film coated tablets blister strips inside their carton. Store at or below 25°C.

What it looks like:

Abiraterone Devatis 500 mg film coated tablets are purple coloured, oval, biconvex film coated tablets.

Ingredients

Active ingredient:

- abiraterone acetate 500 mg

Other ingredients:

- Lactose monohydrate
- Microcrystalline cellulose
- Croscarmellose sodium
- Sodium lauryl sulfate
- Hypromellose
- Colloidal silicon dioxide
- Magnesium stearate

The tablet coating contains:

- Polyvinyl alcohol
- Titanium dioxide
- Macrogol/PEG

- Talc
- Iron oxide red
- Ferrosoferric oxide / Black iron oxide

Sponsor

Devatis Limited
45 Yarrow Street, Invercargill, 9810
New Zealand
Tel: +64 3 211 0080
Fax: +64 3 211 0079
www.devatis.nz

Registration number

.....

This leaflet was prepared in January 2024.