Package leaflet: Information for the user

Abirateron STADA 250 mg, filmomhulde tabletten
Abirateron STADA 500 mg, filmomhulde tabletten
abiraterone acetate

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What <PRODUCT NAME> is and what it is used for

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

When <PRODUCT NAME> 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 chemical known as potassium in your blood.

2. What you need to know before you take <PRODUCT NAME>

Do not take <PRODUCT NAME>
- if you are allergic to abiraterone acetate or any of the other ingredients of this medicine (listed in section 6).
- if you are a woman, especially if pregnant. Abiraterone is for use in male patients only.
- if you have severe liver damage.
- in combination with Ra-223 (which is used to treat prostate cancer).

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 been told you have 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 been told you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions.

Tell your doctor if you have 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. Rarely, failure of the liver to function (called acute liver failure) may occur, which can lead to death.

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

Abiraterone must not be given in combination with Ra-223 due to a possible increase in the risk of bone fracture or death.

If you plan to take Ra-223 following treatment with abiraterone and prednisone/prednisolone, you must wait 5 days before starting treatment with Ra-223.

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

Children and adolescents
This medicine is not for use in children and adolescents. If abiraterone is accidentally ingested by a child or adolescent, go to the hospital immediately and take the package leaflet with you to show to the emergency doctor.

Other medicines and <PRODUCT NAME>
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 abiraterone may increase the effects of a number of medicines including heart medicines, tranquilisers, some medicines for diabetes, 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 abiraterone. This may lead to side effects or to abiraterone not working as well as it should.

Androgen deprivation treatment may increase the risk of heart rhythm problems. Tell your doctor if you are receiving medicine
- 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)].

Tell your doctor if you are taking any of the medicines listed above.

<PRODUCT NAME> with food
- This medicine must not be taken with food (see section 3, "Taking this medicine").
- Taking <PRODUCT NAME> with food may cause side effects.

Pregnancy and breast-feeding

<PRODUCT NAME> is not for use in women.
- **This medicine may cause harm to the unborn child if it is taken by women who are pregnant.**
- **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 and use any tools or machines.

<PRODUCT NAME> contains lactose and sodium
- 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 contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take <PRODUCT NAME>

Always take this medicine exactly as your doctor or pharmacist 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 / two tablets) once a day.

Taking this medicine
- Take this medicine by mouth.
- **Do not take <PRODUCT NAME> with food**.
- **Take <PRODUCT NAME> at least one hour before or at least two hours after eating** (see section 2, "<PRODUCT NAME> with food").
- Swallow the tablets whole with water.
- Do not break the tablets.
- <PRODUCT NAME> 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 <PRODUCT NAME>.
- 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 <PRODUCT NAME> and prednisone or prednisolone.

If you take more <PRODUCT NAME> 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 <PRODUCT NAME>
- If you forget to take <PRODUCT NAME> or prednisone or prednisolone, take your usual dose the following day.
- If you forget to take <PRODUCT NAME> or prednisone or prednisolone for more than one day, talk to your doctor without delay.

If you stop taking <PRODUCT NAME>
Do not stop taking <PRODUCT NAME> 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, pharmacist or nurse.

4. Possible side effects

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

Stop taking <PRODUCT NAME> 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, liver function test increases, high blood pressure, urinary tract infection, diarrhoea.
Common (may affect up to 1 in 10 people):
High fat levels in your blood, chest pain, irregular heart beat (atrial fibrillation), 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), abnormal heart rhythm (arrhythmia), muscle weakness and/or muscle pain.
Rare (may affect up to 1 in 1,000 people):
Lung irritation (also called allergic alveolitis).
Failure of the liver to function (also called acute liver failure).
Not known (frequency cannot be estimated from the available data):
Heart attack, changes in ECG - electrocardiogram (QT prolongation), and serious allergic reactions with difficulty swallowing or breathing, swollen face, lips, tongue or throat, or an itchy rash.

Bone loss may occur in men treated for prostate cancer. <PRODUCT NAME> in combination with prednisone or prednisolone may increase bone loss.

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

5. How to store <PRODUCT NAME>

- 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 blister after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 <PRODUCT NAME> contains
- The active substance is abiraterone acetate. Each tablet contains 250 mg or 500 mg abiraterone acetate.
- The other ingredients are:
  Tablet: Croscarmellose sodium, Sodium laurilsulfate, Povidone (E1201), Cellulose, microcrystalline (E460), Lactose monohydrate, Silica, colloidal anhydrous (E551), Magnesium stearate (E470b) (see section 2, "<PRODUCT NAME> contains lactose and sodium").
  Coating: Polyvinyl alcohol (E1203), Titanium dioxide (E171), Macrogol (E1521), Talc (E553b), *For 500 mg only:* Iron oxide red (E172), Iron oxide black (E172)

What <PRODUCT NAME> looks like and contents of the pack

- <PRODUCT NAME> are white to off-white, film-coated tablets, debossed with “250” on one side.
- <PRODUCT NAME> are purple, oval-shaped film-coated tablets, debossed with “500” on one side.
- The tablets are provided in

  250 mg:

  - Aluminium-OPA/Alu/PVC or Aluminium-PVC/PE/PVDC blisters containing 10, 14, 112 & 120 film-coated tablets.
  - Aluminium-OPA/Alu/PVC or Aluminium-PVC/PE/PVDC perforated unit dose blisters containing 10x1, 14x1, 112x1 & 120x1 film coated tablets.

  500mg:

  - Aluminium-OPA/Alu/PVC or Aluminium-PVC/PE/PVDC blisters containing 10, 14, 56, 60 & 112 film-coated tablets.
  - Aluminium-OPA/Alu/PVC or Aluminium-PVC/PE/PVDC perforated unit dose blisters containing 10x1, 14x1, 56x1, 60x1 & 112x1 film coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
STADA Arzneimittel AG
Stadastrasse 2-18,
61118 Bad Vilbel,
Duitsland

Manufacturer
Remedica Ltd
Aharnon Street, Limassol Industrial Estate,
3056 Limassol,
Cyprus

STADA Arzneimittel AG
Stadastrasse 2-18,
61118 Bad Vilbel,
Duitsland

This medicinal product is authorised in the Member States of the EEA under the following names:

EE: Abiraterone STADA 250 mg õhukese polümeerikattega tabletid
Abiraterone STADA 500 mg õhukese polümeerikattega tabletid
LT: Abiraterone STADA 250 mg plėvele dengtos tabletės
Abiraterone STADA 500 mg plėvele dengtos tabletės
LV: Abiraterone STADA 250 mg apvalkotās tabletes
Abiraterone STADA 500 mg apvalkotās tabletes
NL: Abirateron STADA 250 mg, filmomhulde tabletten
Abirateron STADA 500 mg, filmomhulde tabletten

This leaflet was last revised in juli 2022.