Package leaflet: Information for the user
Abiraterone 250 mg Film-coated Tablets
Abiraterone 500 mg Film-coated Tablets
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 Abiraterone tablets are and what they are used for

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

When this medicine 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 Abiraterone tablets

Do not take Abiraterone tablets
- 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. This medicine 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 acetate 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 acetate 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 acetate 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 tablets are 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 Abiraterone tablets
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 tablets 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 tablets. This may lead to side effects or to Abiraterone tablets not working as well as they 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.

Abiraterone tablets with food
- This medicine must not be taken with food (see section 3, "Taking this medicine").
- Taking Abiraterone with food may cause side effects.

Pregnancy and breast-feeding
Abiraterone tablets are 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.**

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

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

Abiraterone tablets contain lactose and sodium
- This medicine 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 contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Abiraterone tablets

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 Abiraterone 250 mg film-coated tablets or two Abiraterone 500mg film-coated tablets) once a day.

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

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

If you stop taking Abiraterone tablets
Do not stop taking Abiraterone tablets 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 Abiraterone tablets 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. Abiraterone tablets 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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Abiraterone tablets
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 and bottle label 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 Abiraterone tablets contain
The active substance is abiraterone acetate. Each tablet contains 250 mg or 500mg abiraterone acetate.
The other ingredients are:
- *Tablet*: Croscarmellose sodium, Sodium laurilsulfate, Povidone (e12021), Cellulose, microcrystalline (E460), Lactose monohydrate, Silica, colloidal anhydrous (E551), Magnesium stearate (E470b) (see section 2, "Abiraterone 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 Abiraterone tablets looks like and contents of the pack
Abiraterone 250 mg film-coated tablets are white to off-white, film-coated tablets, debossed with "250" on one side, with dimensions 14 mm x 7 mm.

Abiraterone 500 mg film-coated tablets are purple, oval-shaped film-coated tablets, debossed with "500" on one side, with dimensions 19 mm x 10 mm

The film-coated tablets are packed in Aluminium-OPA/Alu/PVC blisters or Aluminium-PVC/PE/PVDC blisters or HDPE bottles.
- 250 mg:
  - blister pack sizes of 84, 112 or 120 tablets
  - 84x1, 112x1 or 120x1 tablets in perforated unit dose blisters
  - bottles of 120 tablets
- 500mg:
  - blister pack sizes of 14, 28, 56, 60, 84 or 112 tablets
  - 56x1, 60x1, 84x1, or 112x1 tablets in perforated unit dose blisters
  - bottles of 60 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

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

Other formats
To request a copy of this leaflet in braille, large print or audio please call 01484 848164.

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