

## **Package leaflet: Information for the user**

### **Abiraterone Teva 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 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**

1. What Abiraterone Teva is and what it is used for
2. What you need to know before you take Abiraterone Teva
3. How to take Abiraterone Teva
4. Possible side effects
5. How to store Abiraterone Teva
6. Contents of the pack and other information

#### **1. What Abiraterone Teva is and what it is used for**

Abiraterone Teva 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. Abiraterone Teva stops your body from making testosterone; this can slow the growth of prostate cancer.

When Abiraterone Teva 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 Teva**

##### **Do NOT take Abiraterone Teva**

- 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 Teva 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 Teva 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 Teva 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 Teva 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 Teva 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 Abiraterone Teva**

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 Teva 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 Teva. This may lead to side effects or to Abiraterone Teva 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.

### **Abiraterone Teva with food**

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

### **Pregnancy and breast-feeding**

#### **Abiraterone Teva is NOT for use in women.**

- **This medicine may cause harm to the unborn child if it is taken by women who are pregnant.**
- **Women who are pregnant or may be pregnant should wear gloves if they need to touch or handle Abiraterone Teva.**
- **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.

### **Abiraterone Teva contains lactose and sodium**

Abiraterone Teva 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 medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially ‘sodium-free’.

## **3. How to take Abiraterone Teva**

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 (two tablets) once a day.

### **Taking this medicine**

- Take this medicine by mouth.
- **Do not take Abiraterone Teva with food.** Taking Abiraterone Teva with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects.
- Take Abiraterone Teva tablets as a single dose once daily on an empty stomach. Abiraterone Teva must be taken at least two hours after eating and food must not be eaten for at least one hour after taking Abiraterone Teva (see section 2, “Abiraterone Teva with food”).
- Swallow the tablets whole with water.
- Do not break the tablets.
- Abiraterone Teva 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 Abiraterone Teva.
- 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 Teva and prednisone or prednisolone.

### **If you take more Abiraterone Teva 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 Teva**

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

**If you stop taking Abiraterone Teva**

Do not stop taking Abiraterone Teva 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 Abiraterone Teva 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 Teva 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 HPRAs Pharmacovigilance Website: [www.hpra.ie](http://www.hpra.ie) By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Abiraterone Teva

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

Do not store above 25°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 protect the environment.

## 6. Contents of the pack and other information

### What Abiraterone Teva contains

- The active substance is abiraterone acetate. Each film-coated tablet contains 500 mg abiraterone acetate, equivalent to 446.3 mg abiraterone.
- The other ingredients are lactose monohydrate, sodium laurilsulfate, croscarmellose sodium, microcrystalline cellulose, povidone, magnesium stearate and colloidal anhydrous silica. The film-coating contains poly(vinyl) alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b) and iron oxide yellow (E172).

### What Abiraterone Teva looks like and contents of the pack

Abiraterone Teva tablets are yellow, oblong film-coated tablets, debossed with “A436” on one side.

Abiraterone Teva is available in blister packs of 14, 56, 60 and 120 film-coated tablets and perforated unit dose blister packs of 14x1, 56x1, 60x1 and 120x1 film-coated tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Teva B.V., Swensweg 5, 2031GA Haarlem, Netherlands

### Manufacturer

Teva Operations Poland Sp. z.o.o, ul. Mogilska 80, Kraków, 31-546, Poland

Merckle GmbH, Graf-Arco-Str. 3, Ulm, Baden-Wuerttemberg, 89079, Germany

Balkanpharma-Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa, 2600, Bulgaria

**This medicinal product is authorised in the Member States of the European Economic Area under the following names:**

Austria	Abirateron TEVA 500 mg Filmtabletten
Belgium	Abirateron Teva 500 mg filmomhulde tabletten/comprimés péliculés/Filmtabletten
Bulgaria	Абиратерон Тева 500 мг филмирани таблетки Abiraterone Teva 500 mg film-coated tablets
Czech Republic, Denmark, Iceland, Norway, Poland, Sweden	Abirateron Teva
Germany	Abirateron ratiopharm 500 mg Filmtabletten
Estonia, Italy,	Abiraterone Teva
Greece	Abiraterone /Teva

Spain	Abiraterona Teva 500 mg comprimidos recubiertos con película EFG
Finland	Abiraterone ratiopharm 500 mg tabletti, kalvopäällysteinen
France	ABIRATERONE TEVA 500mg, comprimé
Croatia	Abirateron Teva 500 mg filmom obložene tablete
Hungary	Abirateron Teva 500 mg filmtabletta
Ireland	Abiraterone Teva 500 mg film-coated tablets
Lithuania	Abiraterone Teva 500 mg plėvele dengtos tabletės
Latvia	Abiraterone Teva 500 mg apvalkotās tabletes
Netherlands	Abirateron Teva 500 mg, filmomhulde tabletten
Portugal	Abiraterona Teva
Romania	Abirateronă Teva 500 mg comprimate filmate
Slovenia	Abirateron Teva 500 mg filmsko obložene tablete

**This leaflet was last revised in December 2023.**