PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Abiraterone Teva 250 mg Tablets **Abiraterone Teva 500 mg Tablets**

Each tablet of Abiraterone Teva 250 mg contains:
Abiraterone acetate 250 mg
Each tablet of Abiraterone Teva 500 mg contains:
Abiraterone acetate 500 mg
For information regarding inactive ingredients and allergens, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Additional information".
Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Abiraterone Teva is a prescription medicine containing an active ingredient called abiraterone acetate.
Abiraterone Teva inhibits the enzyme CYP17. It is given along with prednisone for the treatment of castration-resistant metastatic prostate cancer.
It is also intended for the treatment of adult males with newly diagnosed high risk metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).
Therapeutic class:
Selective inhibitor of the CYP17 enzyme.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- If you are sensitive (allergic) to abiraterone acetate or to any of the additional ingredients the medicine contains. For the list of additional ingredients see section 6 "Additional Information".
- If you are a woman and especially a pregnant woman. Abiraterone Teva is intended for use in males only.
- If you have severe liver damage.
- In combination with Ra-223 (which is used to treat prostate cancer).

Do not take the medicine if any of the above applies to you. If you are unsure, consult the doctor or pharmacist before taking the medicine.
Special warnings regarding the use of the medicine:
Before treatment with Abiraterone Teva, tell the doctor:
- If you have liver problems.
- If you have high blood pressure, heart failure or low levels of potassium in the blood (low levels of potassium in the blood may increase the risk of heart rhythm problems).
- If you have other heart problems or blood vessel problems.
- If you have an irregular heart rhythm or a rapid heart rhythm.
- If you have shortness of breath.
- If you have gained weight rapidly.
- If you have swelling in your feet, ankles or legs.
- If you have taken in the past a medicine called ketoconazole to treat prostate cancer.
- If you have high blood sugar levels.

Consult the doctor about possible effects on your bones.
Consult the doctor about the need to take this medicine with a medicine called prednisone.
Tell your doctor if you are aware of any heart or blood vessel problems, including heart rhythm problems (arrhythmia) or if you are being treated with medicines for these conditions.
Tell your doctor if you have yellowish skin or eyes, dark urine, severe nausea or vomiting. All these may be symptoms of liver problems. Rarely, failure of liver function (called acute liver failure) may occur and can lead to death.
You may suffer from a decrease in red blood cells, reduced sex drive (libido), muscle weakness and muscle pain.
Do not take Abiraterone Teva in combination with Ra-223 due to the possibility of increased risk of bone fractures or death.
If you plan to take Ra-223 following treatment with Abiraterone Teva and prednisone, you must wait 5 days before starting treatment with Ra-223.
If you are not sure if the mentioned effects are relevant to you, talk to your doctor or pharmacist before taking this medicine.
Children and adolescents:
The medicine is not intended for use in children or adolescents.
If a child or adolescent has accidentally swallowed this medicine, proceed to the hospital immediately with the medicine leaflet in order to show it to the doctor.
Tests and follow-up:
Abiraterone Teva may affect the liver, but you may not have any symptoms. The doctor will occasionally perform blood tests during treatment with Abiraterone Teva in order to check liver function.
Drug interactions:
If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.
Abiraterone Teva can increase the effect of certain medicines including heart medicines, tranquilizing medicines, certain medicines for the treatment of diabetes, nutritional supplements (such as: St. John's wort) and other medicines. The doctor may decide to change the dosage of these medicines. In addition, some medicines may increase or decrease the effect of Abiraterone Teva. This effect may lead to the occurrence of Abiraterone Teva side effects or alternatively, impair the effectiveness of Abiraterone Teva.
Other medicines taken with Abiraterone Teva:
Androgen deprivation medicines may increase the risk of heart rhythm problems. Inform the doctor if you are receiving:
- Medicines for the treatment of heart rhythm disorders (such as: quinidine, procainamide, amiodarone and sotalol).
- Medicines that increase the risk of heart rhythm problems (such as: methadone – for pain relief and detoxification of drug addiction, moxifloxacin – an antibiotic, antipsychotic medicines – for serious mental problems).

It is advisable to make a list of all the medicines you are taking in order to inform your doctor or pharmacist.
Use of the medicine and food:
Do not take Abiraterone Teva with food. Taking Abiraterone Teva with food may cause side effects.
Do not eat anything for at least two hours before taking Abiraterone Teva and at least one hour after taking Abiraterone Teva.
Pregnancy and breastfeeding:
Abiraterone Teva is not intended for use in women.
- This medicine may harm the fetus if taken during pregnancy.
- Women who are pregnant or may be pregnant should wear gloves if they come into contact with Abiraterone Teva.
- A man who is having sexual intercourse with a woman who could become pregnant, should use a condom in addition to another effective contraception.
- A man who is having sexual intercourse with a pregnant woman should use a condom to protect the fetus.

Driving and operating machinery:
Abiraterone Teva is not expected to affect the ability to drive and to operate machinery.
Important information about some of the ingredients of the medicine:
- Abiraterone Teva contains lactose. If you know that you have an intolerance to certain sugars, refer to your doctor before starting to take Abiraterone Teva.
- Each tablet of Abiraterone Teva 250 mg contains approximately 145 mg of lactose and 6.5 mg of sodium.
- Each tablet of Abiraterone Teva 500 mg contains approximately 90 mg of lactose and 8.8 mg of sodium. This should be taken into account in patients who are on a sodium-restricted diet.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.
The dosage and treatment regimen will be determined only by the doctor. Abiraterone Teva should be taken with prednisone according to the instructions you received from the doctor.
The accepted dosage for metastatic castration-resistant prostate cancer (CRPC) is generally 1,000 mg once a day (4 tablets of Abiraterone Teva 250 mg or 2 tablets of Abiraterone Teva 500 mg), in combination with 5 mg prednisone treatment twice a day.
The accepted dosage for metastatic hormone-sensitive prostate cancer (mHSPC) is generally 1,000 mg once a day (4 tablets of Abiraterone Teva 250 mg or 2 tablets of Abiraterone Teva 500 mg), in combination with 5 mg prednisone treatment once a day.
Do not exceed the recommended dose.
The doctor may change the dosage as needed.
How to use the medicine:
- Swallow Abiraterone Teva tablets whole.
- Halving the tablet is forbidden.
- Do not pulverize, crush or chew the tablets.
- Swallow Abiraterone Teva tablets with water.
- Take Abiraterone Teva on an empty stomach. **Do not take Abiraterone Teva with food.** Taking Abiraterone Teva with food may lead to the absorption of a larger amount of the medicine than is required, which may cause side effects. Do not eat anything for at least two hours before taking Abiraterone Teva and at least one hour after taking Abiraterone Teva.
- Abiraterone Teva is taken together with a medicine called prednisone. Take prednisone according to the doctor's instructions.
- Take prednisone every day while using Abiraterone Teva.
- It may be necessary to change the dosage of prednisone if there is a change in your medical condition. The doctor will tell you if you need to change the amount of prednisone you are taking. Do not stop taking prednisone unless the doctor instructs you to stop.

Instructions for opening the bottle package:
The plastic bottle comes with a child-proof cap. Open the cap according to the following instructions:
- Press the plastic cap downwards while turning it counter-clockwise
- Remove the cap

If you have accidentally taken a higher dosage than recommended or if a child has accidentally swallowed the medicine, immediately contact a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
If you forget to take a dose of Abiraterone Teva or prednisone, take the next dose the following day at the usual time.
If you forget to take more than one dose of Abiraterone Teva or prednisone, consult the doctor immediately.
Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop taking Abiraterone Teva or prednisone without first consulting the doctor.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Abiraterone Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Stop taking the medicine and inform the doctor immediately if you experience any of the following symptoms:
Muscle weakness, muscle twitches or palpitations. These may be signs of low levels of potassium in the blood.
Additional side effects:
Very common side effects – side effects that occur in more than one out of ten users:
- Fluid in the legs or feet.
- Low level of potassium in the blood.
- Rise in liver function values.
- High blood pressure.
- Urinary tract infection.
- Diarrhea.

Common side effects – side effects that occur in 1-10 out of 100 users:
- High level of blood lipids.
- Chest pain.
- Irregular heartbeats (atrial fibrillation).
- Heart failure.
- Rapid heart rhythm.
- A severe infection called sepsis.
- Bone fractures.
- Indigestion.
- Blood in the urine.
- Rash.

Uncommon side effects – side effects that occur in 1-10 out of 1,000 users:
- Adrenal gland problems (related to a problem in the balance of salts and fluids).
- Irregular heart rhythm (arrhythmia).
- Muscle weakness and/or muscle pain.

Rare side effects – side effects that occur in 1-10 out of 10,000 users:
- Lung irritation (allergic inflammation of the alveoli – allergic alveolitis).
- Failure of liver function (acute liver failure).

Side effects with unknown frequency (side effects whose frequency has not yet been determined):
- Heart attack, changes in ECG (QT interval prolongation).
- Severe allergic reactions with difficulty swallowing or breathing.
- Swelling of the face, lips, tongue or throat.
- Itchy rash.

Loss of bone mass can occur in men treated with Abiraterone Teva for the indication of prostate cancer. Abiraterone Teva in combination with prednisone may increase the loss of bone mass.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.
Reporting of side effects:
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Store the medicine at a temperature below 25ºC.
Abiraterone Teva 250 mg tablets:
- Bottles of 30 tablets: the medicine can be used within 60 days from first opening the bottle, but not after the expiry date of the medicine.
- Bottles of 120 tablets: the medicine can be used within 60 days from first opening the bottle, but not after the expiry date of the medicine.
- Bottles of 150 tablets: the medicine can be used within 5 weeks (35 days) from first opening the bottle, but not after the expiry date of the medicine.

The package contains oxygen absorbers. The oxygen absorbers must be left in the package after opening, and the bottle must be closed tightly after use.
Abiraterone Teva 500 mg tablets:
- Bottles of 60 tablets: the preparation can be used until the expiry date (even after the bottle is first opened). The package contains desiccants. The desiccants must be left in the package after opening, and the bottle must be closed tightly after use.
- Blister pack of 60 tablets: the preparation can be used until the expiry date.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose Sodium, Povidone, Sodium Lauryl Sulfate, Magnesium Stearate, Colloidal Silicon Dioxide, Titanium Dioxide
Abiraterone Teva 250 mg also includes: Talc, Polyvinyl Alcohol, Polyethylene Glycol.
Abiraterone Teva 500 mg also includes: Polyvinyl alcohol part hydrolysed, Macrogol 4000, Talc and Iron Oxide Yellow.
What does the medicine look like and what are the contents of the package:
Abiraterone Teva 250 mg is a white, film-coated, oval tablet. One side of the tablet is debossed with "TEVA" and the other side is debossed with "1125".
Abiraterone Teva 500 mg is a yellow, film-coated, elongated tablet. One side of the tablet is debossed with "A436" and the other side is plain.
Abiraterone Teva 250 mg is marketed in plastic bottles containing 30 tablets, 120 tablets or 150 tablets. In addition to the tablets, the bottles also contain oxygen absorbers.
Do not swallow the oxygen absorbers, and leave them in the bottle.
Abiraterone Teva 500 mg is marketed in a blister pack containing 60 tablets or in plastic bottles of 60 tablets. The bottles also contain desiccants. Do not swallow the desiccants, and leave them in the bottle.
Not all package sizes may be marketed.
Name and address of the manufacturer and marketing authorization holder: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.
The leaflet was revised in December 2022 in accordance with the Ministry of Health guidelines.
Registration numbers of the medicines in the national drug registry of the Ministry of Health:
Abiraterone Teva 250 mg: 158-83-34649
Abiraterone Teva 500 mg: 167-51-35521

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