

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

The medicine is dispensed with a doctor's prescription only

**Abivenir 250 mg
Tablets**

Active ingredient and its quantity

abiraterone acetate 250 mg

Inactive ingredients and allergens in the preparation- see section 2 "Before using the medicine" and section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Abivenir 250 mg is a prescription medicine containing an active ingredient called abiraterone acetate. Abivenir 250 mg is a CYP17 enzyme inhibitor. This medicine is given in combination with prednisone for the treatment of:

- metastatic castration-resistant prostate cancer.
- adult males with newly diagnosed high risk metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT).

Therapeutic group:

Specific inhibitor of the enzyme CYP17

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to abiraterone acetate or to any of the additional ingredients contained in the medicine. For a list of the additional ingredients, see section 6 "Further Information".
- If you are a woman, and especially a pregnant woman. Abivenir 250 mg is intended for use in males only.
- If you suffer from severe liver damage.
- In combination with Ra-223 (used to treat prostate cancer).

Do not take the medicine if any of the above applies to your condition. If you are not sure, consult with your doctor or pharmacist before taking the medicine.

Special warnings regarding use of the medicine

Before treatment with Abivenir 250 mg, talk to the doctor:

- If you suffer from liver problems.
- If you suffer from high blood pressure, heart failure, or low blood potassium levels (low blood potassium levels may increase the risk of heart rhythm problems).
- If you suffer from other heart problems or blood vessel problems.
- If you suffer from an irregular heart rate or a rapid heart rate.
- If you suffer from shortness of breath.
- If you have gained weight rapidly.

- If you have swelling in the feet, ankles, or legs.
- If you have taken in the past a medicine called ketoconazole to treat prostate cancer.
- On the need to take this medicine with a medicine called prednisone.
- About possible effects on your bones.
- If you have high blood sugar levels.
- Tell your doctor if you are aware of any heart or blood vessel problems, including heart rhythm problems (arrhythmia), or you are being treated with medications for these conditions.
- Tell your doctor if you have yellowish skin or eyes, dark urine, severe nausea or vomiting. All these could be symptoms of liver problems. Rarely, failure of liver function (called acute liver failure) may occur and could lead to death.
- You may suffer from a decrease in red blood cells, reduced sex drive (libido), muscle weakness and muscle pain.
- Abivenir 250 mg must not be taken in combination with Ra-223 due to an increased risk of bone fractures or death.
- If you plan to take Ra-223 following treatment with Abivenir 250 mg and prednisone, you must wait 5 days before starting treatment with Ra-223.

If you are not sure if the mentioned effects apply to you, talk to your doctor or pharmacist before taking the medicine.

Children and adolescents

The medicine is not intended for use in children or adolescents. If a child or adolescent accidentally swallowed the medicine, proceed to the hospital immediately with the medicine package in order to show it to the doctor.

Tests and follow up

Abivenir 250 mg could affect your liver, and you may not have any symptoms. Your doctor will occasionally perform blood tests during treatment with Abivenir 250 mg 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 pharmacist.

Abivenir 250 mg may increase the effects of a number of medicines, including heart medicines, tranquilizers, some medicines for treatment of diabetes, nutritional supplements (such as St. John's wort) and other medicines. It is possible that the doctor may decide to change the dosage of these medicines. In addition, some medicines may increase or decrease the effect of Abivenir 250 mg. This effect may cause side effects to occur or, alternatively, impair the effectiveness of Abivenir 250 mg.

Other medicines taken with Abivenir 250 mg

Androgen deprivation medications may increase the risk of heart rhythm problems. Inform the doctor if you are receiving:

- medicines to treat heart rhythm problems (e.g., quinidine, procainamide, amiodarone and sotalol).
- medicines known to increase the risk of heart rhythm problems (e.g., methadone – for pain relief and detoxification from drug addiction, moxifloxacin – an antibiotic, antipsychotics – for serious mental illnesses).

It is advisable to prepare 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 Abivenir 250 mg with food. Taking Abivenir 250 mg with food may cause the body to absorb a quantity larger than required, which may cause side effects. Take Abivenir 250 mg tablets as a single dose once a day on an empty stomach. Take Abivenir 250 mg at least 2 hours after the meal and do not eat for at least one hour after taking Abivenir 250 mg.

Pregnancy, breastfeeding and fertility

Abivenir 250 mg is not intended for use in women.

This medicine may harm the fetus if taken during pregnancy.

Women who are pregnant or may become pregnant should wear gloves if they come into contact with Abivenir 250 mg.

A man who has sexual intercourse with a woman who could become pregnant should use a condom and another effective contraceptive measure.

A man who has sexual intercourse with a pregnant woman should use a condom to protect the fetus.

Driving and operating machinery

Abivenir 250 mg is not expected to affect the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Abivenir 250 mg contains lactose. If you know that you have intolerance to certain sugars, refer to your doctor before starting to take Abivenir 250 mg.

Abivenir 250 mg contains less than 1 mmol (23 mg) sodium in 4 tablets, which is the daily dose. Therefore, it is essentially sodium-free.

3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Abivenir 250 mg should be taken with prednisone in accordance with the instructions you received from the doctor.

The usual dosage is generally 4 tablets of Abivenir 250 mg daily (1,000 mg per day).

For metastatic castration-resistant prostate cancer (CRPC), take Abivenir 250 mg together with 5 mg prednisone twice daily.

For metastatic hormone-sensitive prostate cancer (mHSPC), take Abivenir 250 mg together with 5 mg prednisone daily.

Do not exceed the recommended dose.

It is possible that the doctor may change the dosage as needed.

Taking the medicine:

- Swallow the Abivenir 250 mg tablets whole.
- Do not halve the tablets since there is no score line.
- Do not pulverize, crush or chew the tablets.
- Swallow Abivenir 250 mg tablets with water.
- Take Abivenir 250 mg on an empty stomach. Do not take Abivenir 250 mg with food. Taking Abivenir 250 mg with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects. Do not eat anything for at least

two hours before taking Abivenir 250 mg and for at least one hour after taking Abivenir 250 mg.

- Abivenir 250 mg is taken together with a medicine called prednisone. Take the prednisone according to the doctor's instructions.
- Take prednisone every day while using Abivenir 250 mg.
- It may be necessary to change the dose of prednisone if there is a change in your medical condition. The doctor will instruct you on whether 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:

The plastic bottle comes with a child-resistant cap. Open the cap according to the following instructions:

- Press the plastic cap downwards while turning it counter-clockwise
- Remove the cap

Child-resistant caps have significantly lowered the annual number of cases of poisoning due to medicines.

If you took a higher dosage than recommended, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take a dose of Abivenir 250 mg or prednisone, take the next dose the following day at the usual time.

If you forgot to take more than one dose of Abivenir 250 mg or prednisone, consult the doctor immediately.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking Abivenir 250 mg or prednisone without first consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Abivenir 250 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking the medicine and refer to the doctor immediately if you experience any of the following effects:

Muscle weakness, muscle twitches or a pounding heart (palpitations). These may be signs of low blood potassium levels.

Additional side effects:

Very common side effects – effects that occur in more than one in ten users:

- Fluid in your legs or feet
- Low blood potassium level

- Rise in liver function values
- High blood pressure
- Urinary tract infection
- Diarrhea

Common side effects – effects that occur in 1-10 in 100 users:

- High blood fat level
- Chest pain
- Irregular heartbeat (atrial fibrillation)
- Heart failure
- Rapid heart rate
- Severe infection called sepsis
- Bone fractures
- Indigestion
- Blood in urine
- Rash

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- Adrenal gland problems (related to a problem in the balance of salts and fluids)
- Abnormal heart rhythm (arrhythmia)
- Muscle weakness and/or muscle pain

Rare side effects – effects that occur in 1-10 in 10,000 users:

- Lung irritation (allergic alveolitis)
- Failure of liver function (called acute liver failure)

Side effects whose frequency is unknown:

Heart attack, changes in ECG (QT interval prolongation), severe allergic reactions with difficulty in swallowing or breathing, swelling of the face, lips, tongue or throat, or an itchy rash.

Loss of bone mass may occur in men treated for prostate cancer with Abivenir 250 mg. Abivenir 250 mg in combination with prednisone may increase 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 the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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 below 25 degrees Celsius.
- Shelf life after first opening: 120 days. Store below 25 degrees Celsius.
- Protect from light.
- Store Abivenir 250 mg tablets in the original package.
- Do not discard any unused medicine into the household waste bin or into the local wastewater system. Ask the pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, sodium lauryl sulfate, magnesium stearate, colloidal silicon dioxide.

What the medicine looks like and the contents of the package:

- Abivenir 250 mg tablets are white to off-white in color, oval shaped, debossed with "A" on one side and "250" on the other side.
- The tablets are provided in a plastic bottle with a plastic, child-resistant cap.
- Each bottle contains 120 tablets. Each carton contains one bottle.

Importer and Registration Holder's name and address: BioAvenir Ltd., 1 David Hamelech St., Herzeliya Pituach 4666101, Israel.

Manufacturer's name and address: AIZANT DRUG RESEARCH SOLUTIONS PVT. LTD., INDIA Survey No. 172/173, Apparel Park Road, Dulapally Village; Qutbullapur Mandal, Hyderabad, Telangana 500100 India.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 172-52-37297-99

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