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

This medicine is dispensed with a doctor's prescription only

Abiraterone Medomie 250 mg

Tablets

Active ingredient and its quantity

Abiraterone acetate 250 mg, equivalent to 223 mg of abiraterone.

Inactive ingredients and allergens in the preparation – see section 2 "Important information about some of the medicine's ingredients" and section 6 "Further Information".

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

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Abiraterone Medomie 250 mg is a prescription medicine containing an active ingredient called abiraterone acetate. Abiraterone Medomie 250 mg is a CYP17 enzyme inhibitor, 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 this 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, especially a pregnant woman. Abiraterone Medomie 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 the use of the medicine

Before treatment with Abiraterone Medomie 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
- About 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 medication for these conditions.

• Tell your doctor if you have yellowish skin or eyes, darkening of the 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.

• Abiraterone Medomie 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 Abiraterone Medomie 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 leaflet in order to show it to the doctor.

Tests and follow-up

Abiraterone Medomie 250 mg could affect your liver, and you may not have any symptoms. Your doctor will occasionally perform blood tests during treatment with Abiraterone Medomie 250 mg to check liver function.

Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription medicines or nutritional supplements, tell your doctor or pharmacist.

Abiraterone Medomie 250 mg may increase the effects of a number of medicines, including heart medicines, tranquilisers, 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 Abiraterone Medomie 250 mg. This effect may cause side effects to occur or, alternatively, impair the effectiveness of Abiraterone Medomie 250 mg.

<u>Other medicines taken with Abiraterone Medomie 250 mg</u>

Androgen deprivation medication may increase the risk of heart rhythm problems. Inform your 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 Abiraterone Medomie 250 mg with food. Taking Abiraterone Medomie 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. Take Abiraterone Medomie 250 mg tablets as a single dose once daily on an empty stomach. Abiraterone Medomie 250 mg must be taken at least two hours after a meal and food must not be eaten for at least one hour after taking Abiraterone Medomie 250 mg.

Pregnancy, breastfeeding and fertility

Abiraterone Medomie 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 Abiraterone Medomie 250 mg.

A man who has sexual intercourse with a woman who could become pregnant should use a condom in addition to 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

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

Important information about some of the medicine's ingredients

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

Abiraterone Medomie 250 mg contains sodium.

The total theoretical amount of sodium contained in an Abiraterone Medomie tablet is 10.25 mg.

This should be taken into account in patients who are on a controlled sodium diet.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to your doctor's instructions.

You should check with the doctor or pharmacist if you are unsure about the dosage or treatment regimen with this medicine.

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

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

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

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

For metastatic hormone-sensitive prostate cancer (mHSPC), take Abiraterone Medomie 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 Abiraterone Medomie 250 mg tablets whole.

• Do not halve the tablets, since there is no score line.

• Do not pulverize, crush or chew the tablets.

• Swallow Abiraterone Medomie 250 mg tablets with water.

- Take Abiraterone Medomie 250 mg on an empty stomach. Do not take Abiraterone Medomie 250 mg with food. Taking Abiraterone Medomie 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. Abiraterone Medomie 250 mg must be taken at least two hours after a meal and food must not be eaten for at least one hour after taking Abiraterone Medomie 250 mg.
- Abiraterone Medomie 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 Abiraterone Medomie 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-proof cap. Open the cap according to the following instructions:

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

Child-proof caps have significantly lowered the annual number of cases of poisoning due to medicines. However, if you have difficulty opening the package, you can ask the pharmacist to remove the cap's safety mechanism and replace it with a regular, easy-to-open cap.

If you took a higher dosage than recommended, or if a child has accidentally swallowed the medicine, immediately consult 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 Abiraterone Medomie 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 Abiraterone Medomie 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 Abiraterone Medomie 250 mg or prednisone without first consulting the doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take a medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS

As with any medicine, the use of Abiraterone Medomie 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 beat (palpitations). These may be signs of low blood potassium levels.

Additional side effects:

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

- 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 users in 100:

- High level of blood lipids
- Chest pain
- Irregular heart beat (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 users in 1,000:

- 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 users in 10,000:

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

Side effects with unknown frequency:

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 Abiraterone Medomie 250 mg. Abiraterone Medomie 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 this leaflet, consult your 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 this 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 25^0C.

- Shelf life after first opening: 120 days, when stored at 30^0C.
- Do not discard any remaining 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 to protect the environment.

6. FURTHER INFORMATION

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

Lactose Monohydrate, Microcrystalline Cellulose, Croscarmellose sodium, Povidone 30, Sodium lauryl sulfate, Colloidal silicon dioxide and Magnesium Stearate.

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

  Abiraterone Medomie 250 mg tablets are white to off-white in color, oval shaped, imprinted with “ABR” on one side and “250” on the other side.
- The tablets are provided in a plastic bottle with a plastic cap that is resistant to accidental opening by a child.
- Each bottle contains 120 tablets.

Registration holder's name and address: Medomie Pharma Ltd.,

POB 816, Giv'atayim 5358305, Israel.

Manufacturer's name and address: MSN Laboratories Private Limited,

Telangana 509228, India.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 171-35-37168-99

This leaflet was revised in August 2023 according to Ministry of Health guidelines.