

ABIRATERONE TARO 250 mg FILM COATED TABLETS

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Active ingredient and its quantity

Each tablet of Abiraterone Taro 250 mg contains:

Abiraterone acetate 250 mg

Each tablet of Abiraterone Taro 500 mg contains:

Abiraterone acetate 500 mg

Inactive ingredients and allergens in the preparation – see section 2 “Important information about some of the ingredients of 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 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 THE MEDICINE INTENDED FOR?

Abiraterone Taro is a prescription medicine containing an active ingredient called abiraterone acetate.

Abiraterone Taro is a CYP17 inhibitor indicated:

- in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.
- for the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT).

Therapeutic group:

Other hormone antagonists and related agents.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are hypersensitive (allergic) to abiraterone acetate or to any of the additional ingredients contained in the medicine. For the list of the additional ingredients, see section 6 “Further Information”.
- If you are a woman, and especially a pregnant woman. Abiraterone Taro 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 apply to your condition. If you are not sure, consult a doctor or pharmacist before taking the medicine.

Special warnings regarding use of the medicine

Before treatment with Abiraterone Taro, tell 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
 - Talk to the doctor regarding the need to take this medicine with a medicine called prednisone
 - Talk to the doctor 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 if you are being treated with medicines for these conditions.
 - Tell your doctor if you have yellowish skin or eyes, darkening of urine, severe nausea or vomiting. 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/or muscle pain.
 - Abiraterone Taro 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 Taro 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 Taro could affect your liver, possibly without having any symptoms. Your doctor will occasionally perform blood tests during treatment with Abiraterone Taro to check liver functions.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking: Abiraterone Taro may increase the effect of a number of medicines, including heart medicines, tranquilisers, certain medicines to treat diabetes, dietary supplements such as St. John's wort, and other medicines.

Your doctor may want to change the dose of these medicines. Also, some medicines may increase or decrease the effect of Abiraterone Taro. This effect may cause side effects to occur or, alternatively,

impair the effectiveness of Abiraterone Taro.

Other medicines taken with Abiraterone Taro

Androgen deprivation medicines 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 of drug addiction, moxifloxacin – an antibiotic, antipsychotics – for serious mental illnesses).

Tell your doctor if you are taking any of the medicines listed above.

Use of the medicine and food

Do not take Abiraterone Taro with food. Taking Abiraterone Taro 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 Taro tablets as a single dose once daily on an empty stomach. Abiraterone Taro must be taken at least two hours after a meal and food must not be eaten for at least one hour after taking Abiraterone Taro.

Pregnancy, breastfeeding and fertility

Abiraterone Taro 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 Taro.

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

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

Driving and operating machinery

Abiraterone Taro is not expected to affect the ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Abiraterone Taro contains lactose. If you know, or have been told by your doctor, that you are intolerant to certain sugars, refer to your doctor before starting to take Abiraterone Taro.

Abiraterone Taro contains less than 1 mmol (equivalent to 23 mg) sodium per 4 tablets of 250 mg or 2 tablets of 500 mg, which are the daily dosage. That is to say that Abiraterone Taro is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of this medicine.

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

Abiraterone Taro should be taken with prednisone in accordance with the instructions you received from the doctor.

The recommended dosage for metastatic castration-resistant prostate cancer (CRPC) is generally 1,000 mg taken once daily (4 tablets of Abiraterone Taro 250 mg or 2 tablets of Abiraterone Taro 500 mg), in combination with 5 mg prednisone twice daily.

The recommended dosage for metastatic hormone-sensitive prostate cancer (mHSPC) is generally 1,000 mg taken once daily (4 tablets of Abiraterone Taro 250 mg or 2 tablets of Abiraterone Taro 500 mg), in combination with 5 mg prednisone once daily.

Do not exceed the recommended dose.

The doctor may change the dosage as needed.

Taking the medicine:

- Swallow Abiraterone Taro tablets whole.
- Do not halve the film coated tablets since there is no score line.
- Do not pulverize, crush or chew the tablets.
- Swallow Abiraterone Taro tablets with water.
- Take Abiraterone Taro on an empty stomach. Do not take Abiraterone Taro with food. Taking Abiraterone Taro with food may cause more of the medicine to be absorbed by the body than is needed and this may cause side effects. Abiraterone Taro must be taken at least two hours after a meal and food must not be eaten for at least one hour after taking Abiraterone Taro.
- Abiraterone Taro is taken in combination with a medicine called prednisone. Take prednisone according to the doctor's instructions.
- Take prednisone every day while using Abiraterone Taro.
- It may be necessary to change the dosage of prednisone if there is a change in your medical condition. The doctor will instruct you on whether to change the amount of prednisone you are taking. Do not stop taking prednisone unless the doctor instructs you to do so.

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

If you have taken 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 forget to take a dose of Abiraterone Taro or prednisone, take the next dose the following day at the usual time.

If you forget to take more than one dose of Abiraterone Taro 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 Taro or prednisone without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take 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 Abiraterone Taro 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 refer to the doctor immediately if you experience any of the following symptoms:

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:**

- Fluids in the legs or feet
- Low blood potassium level
- Increase in liver function values
- High blood pressure
- Urinary tract infection
- Diarrhea

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

- High fat levels in your blood
- 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 whose frequency is unknown (side effects whose frequency has not yet been determined):

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

Loss of bone mass may occur in men treated with Abiraterone Taro for prostate cancer.

Abiraterone Taro in combination with prednisone may increase loss of bone mass.

If you experience any side effect, if any side effect gets worse, or if you experience 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 “Reporting Side Effects due to Medical Treatment” on the Ministry of Health 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 SHOULD THE MEDICINE BE STORED?

- 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 unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine below 25 Celsius degrees.
- Shelf life after first opening of the bottle: until end of shelf life.
- 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 to protect the environment.

6. FURTHER INFORMATION

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

Sodium laurilsulfate; Lactose monohydrate; cellulose, microcrystalline 102 (E460); croscarmellose sodium; povidone, K 30 (E1201); magnesium stearate (E470b); silica, colloidal anhydrous (E551)

Abiraterone Taro 250 mg also contains:

Poly(Vinyl alcohol) (E1203); Titanium dioxide (E171); Macrogol 3350 (E1521); Talc (E533b)

Abiraterone Taro 500 mg also contains:

Poly(Vinyl alcohol) (E1203); Titanium dioxide (E171); Macrogol 3350 (E1521); Talc (E533b); iron oxide red (E172); iron oxide black (E172)

What does the medicine look like and what are the contents of the package:

Abiraterone Taro 250 mg tablets:

- White to off-white, oval-shaped film-coated tablets, without a score line, debossed with "250" on one side.
- The tablets are provided in two packs: a plastic bottle with a plastic, child-proof cap, and a blister pack.
- Each bottle contains 120 tablets. Each carton contains one bottle.
- Each bottle contains oxygen absorber canister.
- Each blister pack contains 10 or 120 film-coated tablets.

Abiraterone Taro 500 mg tablets:

- Purple, oval-shaped film-coated tablets, without a score line, debossed with "500" on one side.
- The tablets are provided in two packs: a plastic bottle with a plastic, child-proof cap, and a blister pack.
- Each bottle contains 60 tablets. Each carton contains one bottle.
- Each bottle contains oxygen absorber canister.
- Each blister pack contains 10 or 60 film-coated tablets.

Not all pack sizes may be marketed.

Registration holder: Taro International LTD., 14 Hakitor St., Haifa Bay 2624761, Israel.

Manufacturer: Remedica LTD., Aharnon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus.

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:

Abiraterone Taro 250 mg: 178-07-37298-99

Abiraterone Taro 500 mg: 178-08-37299-99

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למידע נוסף על התכשיר ולעלוניו מעודכנים בשפות עברית, ערבית ואנגלית סירקו את הקודים הבאים:

For further information about the medicinal product and for updated patient leaflets in Hebrew, Arabic and English, please scan the codes:

למידע נוסף על המוצר המידיקי ולעלוניו מעודכנים בשפות עברית, ערבית ואנגלית, סירקו את הקודים הבאים:

250 mg



<https://israeldrugs.health.gov.il/#!/medDetails/178%2007%2037298%2099>

500 mg



<https://israeldrugs.health.gov.il/#!/medDetails/178%2008%2037299%2099>

ניתן לפנות לבעל הרישום של התכשיר בבקשה לקבל עלון מודפס לצרכן בשפה האנגלית בכתובת הדואר האלקטרוני Info@taro.com או בטלפון מספר 1-800-464-664.

For a printed copy of the patient information leaflet in English, please contact the registration holder by email Info@taro.com or by phone 1-800-464-664.

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