

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

The medicine is dispensed with a doctor's prescription only

Casodex[®] 50 mg

Tablets

Composition:

Each tablet contains:

bicalutamide 50 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this 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, 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.

This medicine is not intended for women or children, including pregnant or breast-feeding women.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of prostate cancer.

Therapeutic group:

An anti-androgenic agent that interferes with some of the activities of androgens (male hormones) within the body.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient bicalutamide or to any of the other ingredients of this medicine (please refer to section 6 - Further Information).
- you are already taking a medicine called cisapride or certain anti-histamine medicines (terfenadine, astemizole).

Special warnings regarding use of Casodex

Before starting treatment with Casodex, tell the doctor if:

- You are suffering from a heart or blood vessel problem, including heart rhythm disorders (arrhythmia), or if you are being treated with medicines for any of these problems. The risk of heart rhythm problems can increase when using Casodex.
- You are taking blood thinners or medicines to prevent blood clots.
- You are suffering from liver problems.
- You are suffering from diabetes and are taking "LHRH analogs", including goserelin, buserelin, leuprorelin and triptorelin.

If you go to the hospital, tell the medical staff that you are taking Casodex. You and/or your partner should use birth control while you are taking Casodex and for 130 days after stopping Casodex. Refer to the doctor if you have any questions about birth control.

Drug Interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutrition supplements, tell the doctor or the pharmacist. This is because Casodex may affect the way certain medicines work, and certain medicines may affect the way Casodex works.

Do not take Casodex if you are taking any of the following medicines:

- cisapride (for certain types of indigestion).
- anti-histamine medicines (terfenadine, astemizole).

Tell the doctor or pharmacist if you are taking:

- medicines to treat heart rhythm disorders (e.g., quinidine, procainamide, amiodarone and sotalol).

- Casodex might increase the risk of heart rhythm disorders if used concomitantly with medicines such as:
methadone (for pain relief and part of drug addiction detoxification).
moxifloxacin (an antibiotic).
antipsychotics (for treatment of mental illnesses).
- anti-coagulants (taken by mouth) e.g. warfarin.
- ciclosporin (to suppress the immune system).
- calcium channel blockers (to treat high blood pressure or heart conditions).
- cimetidine (for stomach problems).
- ketoconazole (to treat infections caused by fungi).

Pregnancy, breast-feeding and fertility

Casodex must not be taken by women, including pregnant or breast-feeding women.

Casodex may have an effect on male fertility which could be reversible.

Driving and use of machines

Casodex is not likely to affect you being able to drive or use any tools or machines. However, if you feel sleepy take care with these activities.

Important information about some of the ingredients of the medicine

Casodex contains lactose

The preparation contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking Casodex.

Casodex contains sodium

This medicine contains less than 23 mg sodium per tablet, that is to say essentially sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of this medicine.
- The dosage and the duration of treatment are determined by the doctor in accordance with the ailment from which you are suffering.

- The usual dosage is generally one tablet per day.
- Try to take the tablet at the same time every day.
- **Do not exceed the recommended dose.**

Instructions for use:

- Swallow the tablet whole with water.
- Do not chew, crush or halve the tablet!

If you have taken a higher dosage

If you take an overdose or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and take the package of Casodex with you. An overdose may lead to increased risk of bleeding.

If you forgot to take this medicine at the scheduled time, do not take the forgotten dose; rather, take the next dose at the next scheduled time. Do not take two doses at the same time to compensate for a forgotten dose.

How can you contribute to the success of the treatment?

Complete the treatment recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor: make sure to carefully follow the instructions regarding administration of the medicine and in case of any doubt, refer to 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 Casodex 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.

Allergic reactions

Uncommon side effects (effects occurring in 1-10 of 1,000 users):

The symptoms can include sudden onset of:

- Skin rash, severe itching or hives on the skin (with raised lumps on the skin).
- Swelling of the face, lips, tongue, throat or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.

Refer to a doctor straight away if the above effects occur.

Also refer to the doctor immediately if any of the following side effects occur:

Very common side effects (effects occurring in more than 1 of 10 users):

- Abdominal pains.
- Blood in the urine.

Common side effects (effects occurring in 1-10 of 100 users):

- Yellowing of the skin or whites of the eyes (jaundice) may be a sign of liver function problems or, in rare cases (may affect up to 1 in 1,000 patients), liver failure.

Uncommon side effects (effects occurring in 1-10 of 1,000 users):

- Serious shortness of breath or shortness of breath that suddenly gets worse, which may be accompanied by a cough or fever. These may be signs of an inflammation of the lungs called interstitial lung disease.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Changes in electrocardiogram – a recording of electrical currents in the heart, as recorded by an ECG (QT prolongation).

Other side effects:

Very common side effects (effects occurring in more than 1 of 10 users):

- Dizziness.
- Constipation.
- Nausea.
- Swelling and tenderness of your breasts.
- Hot flushes.
- Feeling weak.
- Swelling.

- Low level of red blood cells (anemia); may cause tiredness or pallor.

Common side effects (effects occurring in 1-10 of 100 users):

- Loss of appetite.
- Reduced sex drive.
- Depression.
- Feeling sleepy.
- Indigestion.
- Wind, flatulence.
- Hair loss.
- Hair re-growth or growth of extra hair.
- Dry skin.
- Itching.
- Skin rash.
- Impotence.
- Weight gain.
- Chest pains.
- Reduced heart function.
- Heart attack.

Rare side effects (effects occurring in 1-10 of 10,000 users):

- Increased skin sensitivity to sunlight.

The preparation may sometimes cause changes in the blood, which will require your doctor to perform certain blood tests.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

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 in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Even when packaged/stored as recommended, medicines may be kept for a limited period only. Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store different medicines in the same package.

Storage conditions:

- Store at a temperature that does not exceed 25°C.

6. FURTHER INFORMATION

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

Lactose monohydrate, sodium starch glycollate, polyvidone, methylhydroxypropyl cellulose, magnesium stearate, titanium dioxide, macrogol 300

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

Film-coated, white, biconvex tablets, with Cdx50 debossed on one side and a logo debossed on the other side. Each package contains 28 tablets.

Manufacturer:

Corden Pharma GmbH, Plankstadt, Germany

License holder:

Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

103 82 28597 00

Casodex is a registered trademark of Juvise Pharmaceuticals.

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