

Package leaflet: Information for the user

Casodex 150 mg film-coated tablets Bicalutamide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Casodex is and what it is used for
2. What you need to know before you take Casodex
3. How to take Casodex
4. Possible side effects
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6. Contents of the pack and other information

1. What Casodex is and what it is used for

Casodex contains a medicine called bicalutamide. This belongs to a group of medicines called 'anti-androgens'.

- Casodex is used to treat prostate cancer.
- It works by blocking the effects of male hormones such as testosterone.

2. What you need to know before you take Casodex

Do not take Casodex:

- if you are a woman.
- if you are allergic to bicalutamide or any of the other ingredients of this medicine (listed in section 6).
- if you are already taking a medicine called cisapride or certain anti-histamine medicines (terfenadine or astemizole).

Casodex must not be given to children.

Do not take Casodex if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Casodex.

Warnings and precautions

Talk to your doctor or pharmacist before taking Casodex:

- if you have problems with your liver. Your doctor may do blood tests before and during your treatment with Casodex.

- if you have any of the following: any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Casodex.
- if 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. Talk to your doctor if you have any questions about birth control.

If you go into hospital, tell the medical staff that you are taking Casodex.

Children and adolescents

Casodex must not be given to children or adolescents.

Tests and checks

Your doctor may do blood tests to check for any changes to your blood.

Other medicines and Casodex

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because Casodex can affect the way other medicines work. Also some other medicines can affect the way Casodex works.

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

- Cisapride (used for some types of indigestion).
- Certain anti-histamines (terfenadine or astemizole).

Casodex might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone, (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illness).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants). Blood thinners or medicines to prevent blood clots. Your doctor may do blood tests before and during your treatment with Casodex.
- Ciclosporin (to suppress your immune system).
- Calcium channel blockers (to treat high blood pressure or some heart conditions).
- Cimetidine (for stomach problems).
- Ketoconazole (to treat infections caused by a fungus).

Pregnancy and breast-feeding

- Casodex must not be given to a woman.

Driving and using machines

Casodex is not likely to affect your ability to drive or use any tools or machines. However, some people may occasionally feel sleepy while taking Casodex. If this happens to you, ask your doctor or pharmacist for advice.

Sunlight or Ultraviolet (UV) light

Avoid direct exposure to excessive sunlight or UV light while you are taking Casodex.

Casodex contains lactose.

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Casodex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Casodex

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet each day. Swallow the tablet whole with a drink of water. Try to take your tablet at the same time each day. Do not stop taking this medicine even if you feel well, unless your doctor tells you to.

Use in children and adolescents

Casodex must not be given to children.

If you take more Casodex than you should

If you take more Casodex than you should, talk to a doctor or go to a hospital straight away.

If you forget to take Casodex

If you forget to take a dose, skip the missed dose and take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following side effects-you may need urgent medical treatment:

Allergic reactions (uncommon, may affect up to 1 in 100 people):

The symptoms can include sudden onset of:

- Rash, itching or hives on the skin.
- Swelling of the face, lips, tongue, throat or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.

Also tell your doctor straight away if you notice any of the following:

Common (may affect up to 1 in 10 people):

- Yellowing of the skin or whites of your eyes (jaundice). These may be signs of liver problems or in rare cases (affects less than 1 in 1,000 people) liver failure.
- Pain in your abdomen.
- Blood in your urine.

Uncommon (may affect up to 1 in 100 people):

Serious shortness of breath or shortness of breath which suddenly gets worse. This may be with a cough or high temperature (fever). These may be signs of an inflammation of the lungs called 'interstitial lung disease'.

Not known (frequency cannot be estimated from the available data):

Changes in ECG (QT prolongation).

Other possible side effects:

Very common (may affect more than 1 in 10 people):

- Skin rash.
- Swelling and tenderness of your breasts.
- Feeling weak.

Common (may affect up to 1 in 10 people):

- Hot flushes.
- Feeling sick (nausea).
- Itching.
- Dry skin.
- Problems getting an erection (erectile dysfunction).
- Putting on weight.
- Reduced sex drive and reduced fertility.
- Hair loss.
- Hair re-growth or growth of extra hair.
- Low levels of red blood cells (anaemia). This may make you feel tired or look pale.
- Loss of appetite.
- Depression.
- Feeling sleepy.
- Indigestion.
- Dizziness.
- Constipation.
- Wind (flatulence).
- Chest pain.
- Swelling.

Rare (affects less than 1 in 1,000 people)

- Increased skin sensitivity to sunlight.

Your doctor may do blood tests to check for any changes to your blood.

Do not be concerned by this list of side effects. You may not get any of them.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Casodex

Keep this medicine out of the sight and reach of children.

Keep your tablets in the container they came in.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Casodex contains

The active substance is bicalutamide 150 mg. Each tablet contains 150 mg bicalutamide.

The other ingredients (excipients) are:

- Tablet core: lactose monohydrate, magnesium stearate, povidone, Sodium Starch Glycolate.
- Film-coating material: hypromellose, macrogol 300, titanium dioxide.

What Casodex looks like and contents of the pack

Casodex 150 mg film-coated tablets are round, biconvex, white film-coated tablets. A logo is impressed on one side and a tablet strength marking is impressed on the other side. Casodex 150 mg film-coated tablets are provided in blister packs of 10, 20, 30, 40, 50, 80, 90, 100, 200, or 14, 28, 56, 84, 140 and 280 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Casodex 150 mg Film-coated Tablets is held by AstraZeneca UK Limited, Silk Road Business Park, Charter Way, Macclesfield, SK10 2NA, United Kingdom.

Casodex 150 mg Film-coated Tablets are manufactured by AstraZeneca UK Ltd, Silk Road Business Park, Macclesfield, Cheshire, SK10 2 NA, UK.

This leaflet was last revised in April 2020