

CASODEX[®] TABLET 50MG

Bicalutamide (50mg)

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What Casodex is used for

Casodex is used to treat prostate cancer.

How Casodex works

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.

Before you use Casodex

- When you must not use it

Do not take Casodex if:

- You are allergic (hypersensitive) to bicalutamide or any of the other ingredients of this medicine.
- You are already taking a medicine called cisapride or certain anti-histamine medicines (terfenadine or astemizole).
- You are a woman.

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.

Casodex must not be given to children.

- Before you start to use it

Check with your doctor or pharmacist before taking 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.
- You are taking blood thinners or medicines to prevent blood clots.
- You have problems with your liver.
- You have diabetes and are already taking an 'LHRH analogue'. These include goserelin, buserelin, leuporelin and triptorelin.
- You go into hospital, tell the medical staff that you are taking Casodex.
- 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.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy 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-histamine medicines (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 illnesses.

Also, tell your doctor if you are taking any of the following medicines:

- Medicines taken by mouth to prevent blood clots (oral anti-coagulants), eg. warfarin, blood thinners or medicines to prevent blood clots.
- 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).

How to use Casodex

- How much to use

Always take Casodex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The usual dose for an adult is one tablet each day.
- Swallow the tablet whole with a drink of water.

- When to use it

Try to take your tablet at the same time each day.

- How long to use it

Do not stop taking this medicine even if you feel well, unless your doctor tells you to.

- If you forget to use it

If you forget to take a dose, skip the missed dose and take the next dose as usual.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

- If you use too much (overdose)

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

While you are using it

- Things you must do

Follow your doctor's advice and continue taking the medication.

- Things you must not do

Stop medication without consulting your doctor.

- Things to be careful of

Pregnancy, breast-feeding and fertility

Casodex must not be taken by women, including pregnant women or mothers who are breast-feeding their babies.

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

Driving and using 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 Casodex

Casodex contains lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some

sugars), talk to your doctor before taking this medicine.

A reduction in glucose tolerance has been observed in males receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in those with pre-existing diabetes. Consideration should therefore be given to monitoring blood glucose in patients receiving Casodex in combination with LHRH agonists.

Side effects

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

Allergic reactions

These are **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.

If this happens to you, **see a doctor straight away**.

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

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

- Pain in your abdomen.
- Blood in your urine.

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 (may affect up to 1 in 1,000 people) liver failure.

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)

- Dizziness.
- Constipation.
- Feeling sick (nausea).
- Swelling and tenderness of your breasts.
- Hot flushes.
- Feeling weak.
- Swelling.
- Low levels of red blood cells (anaemia). This may make you feel tired or look pale.

Common (may affect up to 1 in 10 people)

- 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.
- Being unable to get an erection (impotence).
- Weight gain.
- Chest pain.
- Reduced heart function.
- Heart attack.

Rare (may affect up to 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 possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Casodex

- Storage

- Keep your tablets in the container they came in.
- Do not store above 30°C.
- Keep your tablets in a safe place where children cannot see or reach them. Your tablets could harm them.
- Do not use your tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

- Disposal

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.

Product Description

- What it looks like

Casodex 50 mg Film-coated Tablets are round, white tablets marked with Cdx 50 on one side and a logo on the other side. Casodex 50mg comes in packs of 28 tablets.

- Ingredients

- Active ingredient(s)
The active ingredient is bicalutamide. Each tablet contains 50 mg of bicalutamide.

- Inactive ingredients

The other ingredients are lactose monohydrate, magnesium stearate, hypromellose, macrogol 300, povidone, sodium starch glycolate and titanium dioxide (E171).

- MAL number:

MAL19990958ACRZ

Manufacturer

Corden Pharma GmbH,
Plankstadt, Germany
for AstraZeneca UK Limited.

Product Registration Holder

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