

Cosudex[®]

Bicalutamide 50 mg Tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Cosudex**. It does not contain all the information that is known about **Cosudex**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Cosudex** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Cosudex is used for

Cosudex 50 mg is used to treat prostate cancer.

Cosudex is an anti-androgen medicine. Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens may help the cancer cells to grow. By blocking these hormones, **Cosudex** may slow or stop the growth of cancer cells.

Cosudex 50 mg will be used in combination with other medicines to treat your cancer.

Cosudex should only be taken by men.

Follow all directions given to you by your doctor. They may differ from the information in this leaflet. Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Cosudex is not addictive.

Cosudex is only available with a doctor's prescription.

Before you use Cosudex

When you must not use it

Cosudex must not be taken by women, including pregnant women or mothers who are breast feeding. Women are not normally treated with **Cosudex**.

Do not take Cosudex if you are allergic to bicalutamide or any other ingredients in Cosudex.

Do not give Cosudex to children. There is no experience of its use in children.

Do not take Cosudex after the use by (expiry) date printed on the pack. It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not use Cosudex if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else even if their symptoms seem similar to yours.

You must tell your doctor if:

1. you have allergies to:

- bicalutamide, the active ingredient
- any of the other ingredients listed at the end of this leaflet.
- other anti-androgen medicines
- any other medicines
- any other substances, such as foods, preservatives or dyes

If you have an allergic reaction, you may get a skin rash, hayfever, or have difficulty breathing or feel faint.

2. you have liver problems

It may not be safe for you to take **Cosudex** if you have problems with your liver.

3. you have diabetes and are already taking an LHRH analogue.

4. you have any of the following: 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 in such patients when using **Cosudex**.

5. you are taking **Cosudex**, you and/or your partner should use birth control while you are taking **Cosudex** and for 130 days after stopping **Cosudex**. Talk to your doctor if you have any questions about birth control.

Taking other medicines**Tell your doctor if you are taking any other medicines, including:**

- medicines used to prevent blood clots or blood thinners, including warfarin
- anti-histamines (terfenadine, astemizole)
- medicines for indigestion (cisapride)
- medicines that suppress your immune system (cyclosporin)
- calcium channel blockers (used to treat high blood pressure or some heart conditions)
- medicines that you buy at the chemist, supermarket or health food shop

These medicines may affect the way **Cosudex** works.

Cosudex might interfere with some medicines used to treat heart rhythm problems or might increase the risk of heart rhythm problems when used with some other drugs that can cause heart rhythm abnormalities.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you take any **Cosudex**.

How to take Cosudex

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help. Start taking Cosudex at the same time as the other medicines you are taking to treat your prostate cancer.

How much to take

The usual adult dose is one 50 mg tablet taken each day. **Swallow your Cosudex tablet whole with a full glass of water.**

When to take it

Take Cosudex at about the same time each day. It does not matter if you take **Cosudex** before, with or after food.

How long to take it

Keep taking Cosudex for as long as your doctor or pharmacist tells you.

If you forget to take it

If you miss a dose take it as soon as you remember, as long as it is 12 hours or more before the next dose is due.

If it is less than 12 hours to the next dose do not take the dose you have missed. Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

Things to be careful of

Be careful driving or operating machinery until you know how Cosudex affects you. Some patients may feel dizzy or weak.

While you are using Cosudex

Things you must do

Be sure to keep all your appointments with your doctor so your progress can be checked.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking **Cosudex**.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking **Cosudex**.

Cosudex may affect your sperm (semen) while you are taking it and for some time after you stop taking it. As a precaution, you and/or your partner must use adequate contraception while you are taking **Cosudex** and for at least 130 days after you have stopped taking **Cosudex**.

If you go into hospital, please let the medical staff know you are taking **Cosudex**.

Things you must not do

Do not give Cosudex to anyone else, even if they have the same condition as you.

Do not take Cosudex to treat any other complaints unless your doctor tells you to.

Do not stop taking Cosudex, or change the dosage, without checking with your doctor.

Overdose

Telephone your doctor or the National Poisons Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Cosudex. Even if there are no signs of discomfort or poisoning.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Cosudex.

Cosudex helps most people with prostate cancer, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Allergic Reactions:

These are uncommon (affect less than 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:

- Pain in your stomach
- Blood in your urine
- Yellowing of the skin or whites of your eyes (jaundice). These may be signs of liver problems or liver failure.
- 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'.

Other possible side effects:**Very common (affects 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 (affects less than 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.

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Some people may get other effects while taking **Cosudex**.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Cosudex**.

After using it**Storage**

Keep your tablets in the blister pack until it is time to take them. If you take **Cosudex** out of the blister pack it will not keep well. **Keep the tablets in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.** Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave it in the car on hot days.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What Cosudex looks like

Cosudex 50 mg tablets are white, round film-coated tablets. One side of the tablet is marked CDX 50 and the other side has an arrow shape.

Cosudex tablets are packed in blister foils of 28 tablets.

Ingredients

Each **Cosudex 50 mg** tablet contains 50mg of bicalutamide as the active ingredient, plus

- Lactose
- Sodium starch glycolate
- Povidone
- Magnesium stearate (E572)
- Hypromellose
- Macrogol 300
- Titanium dioxide (E171)

Cosudex does not contain added sucrose, gluten, tartrazine or any other azo dyes.

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