

COSUDEX[®] 50 mg tablets

Bicalutamide

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 for

COSUDEX 50 mg is used in combination with other medicines to treat advanced 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. COSUDEX interferes with some of the actions of these hormones.

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.

Before you use Cosudex

When you must not use it

Do not take COSUDEX if you are a woman.

Do not give COSUDEX to children.

There is no experience of its use in children.

Do not take COSUDEX if you are allergic to bicalutamide or any of the other ingredients in COSUDEX.

Do not take COSUDEX if you are taking cisapride or the antihistamines, terfenadine and astemizole.

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 take 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.

Before you start to use it

You must tell your doctor if:

1. you have allergies to:

- bicalutamide, the active ingredient in COSUDEX
- any of the other ingredients of COSUDEX 50 mg 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, hay fever, 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 heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions.

The risk of you having further heart rhythm problems may increase if you are taking COSUDEX.

Taking other medicines

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

- cisapride (see When you must not use it)
- the antihistamines terfenadine and astemizole (see When you must not use it)
- medicines used to prevent blood clots, especially warfarin as COSUDEX may reduce their

effectiveness which may lead to bleeding and you therefore may need more monitoring

- midazolam
- cyclosporin
- medicines used to treat high cholesterol
- calcium channel blockers
- carbamazepine
- quinidine
- antiviral medicines for HIV infection
- medicines that you buy at the chemist, supermarket or health food shop

These medicines may affect the way COSUDEX works or COSUDEX may affect how these medicines work.

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.

Taking 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.

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.

COSUDEX 50 mg should be started at the same time as the other

medicines you have been given for the treatment of prostate cancer.

It does not matter if you take COSUDEX before, with or after food.

How long to take it

Continue 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 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.

Overdose

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much COSUDEX. Do this even if there are no signs of discomfort or poisoning.

While you are using it

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 lower the dosage, without checking with your doctor.

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.

Side effects

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

COSUDEX helps people with advanced 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.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- hot flushes or sweating
- breast tenderness or changes in breast size
- itching or dry skin, rashes
- increased hairiness or hair loss
- stomach pain or indigestion
- nausea or vomiting
- diarrhoea or constipation
- flatulence (wind)
- dry mouth
- loss of appetite or weight changes
- depression
- unusual tiredness or weakness
- dizziness or light-headedness
- difficulty sleeping
- headache
- chills
- pelvic pain
- decrease in your sexual drive
- inability to get or maintain an erection.

These are possible side effects of COSUDEX.

COSUDEX may also cause a period of low fertility or infertility whilst you are taking it and for a period afterwards. NOTE however that you may not be infertile. As COSUDEX may affect your sperm, effective contraception must be used by you and/or your partner while you are taking COSUDEX and for at least 130 days after you have stopped taking COSUDEX.

Tell your doctor immediately if you notice any of the following:

- frequent urination
- shortness of breath and dizziness when exercising and looking pale (anaemia)
- excessive thirst with weight loss, and passing large amounts of urine.

These side effects may be serious.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen.

- chest pain
- yellowing of the skin or eyes and dark coloured urine
- rash, hives or severe itching of the skin,
- swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing
- swelling of other parts of the body including hands, feet or ankles
- serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever.
- shortness of breath, wheezing or trouble breathing.

These are all serious side effects. You may need urgent medical attention or hospitalisation.

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

Some people may get other effects while taking COSUDEX.

After using Cosudex

Storage

Keep your COSUDEX tablets in the blister foil until it is time to take them.

If you take COSUDEX out of the blister foil, it will not keep well.

Keep it 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.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep your medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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 50 mg of bicalutamide as the active ingredient, plus

- lactose monohydrate
- 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.

Manufacturer

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