COSUDEX®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using COSUDEX?

COSUDEX contains the active ingredient bicalutamide. COSUDEX is used in combination with other medicines to treat advanced prostate cancer.

For more information, see Section 1. Why am I using COSUDEX? in the full CMI.

2. What should I know before I use COSUDEX?

Do not use if you have ever had an allergic reaction to COSUDEX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use COSUDEX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COSUDEX and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use COSUDEX?

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

More instructions can be found in Section 4. How do I use COSUDEX? in the full CMI.

5. What should I know while using COSUDEX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using COSUDEX. • Be sure to keep all your appointments with your

	doctor so your progress can be checked. • Use adequate contraception while you are taking COSUDEX and for at least 130 days after you have stopped taking COSUDEX.
Things you should 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.
Driving or using machines	• Be careful driving or operating machinery until you know how COSUDEX affects you.
Looking after your medicine	• Keep your COSUDEX tablets in the blister foil until it is time to take them.

	• Keep it in a cool, dry place where the temperature stays below 30°C.

For more information, see Section 5. What should I know while using COSUDEX? in the full CMI.

6. Are there any side effects?

Like all medicines, COSUDEX can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

When you take COSUDEX, you can have some serious side effects

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

COSUDEX®

Active ingredient: bicalutamide

Consumer Medicine Information (CMI)

This leaflet provides important information about using COSUDEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COSUDEX.**

Where to find information in this leaflet:

1. Why am I using COSUDEX?
2. What should I know before I use COSUDEX?
3. What if I am taking other medicines?
4. How do I take COSUDEX?
5. What should I know while using COSUDEX?
6. Are there any side effects?
7. Product details

1. Why am I using COSUDEX?

COSUDEX contains the active ingredient bicalutamide. 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 grow. COSUDEX interferes with some of the actions of these hormones.

COSUDEX is used in combination with other medicines to treat advanced prostate cancer.

COSUDEX should only be taken by men.

2. What should I know before I use COSUDEX?

Warnings

Do not use COSUDEX if:

- you are allergic to bicalutamide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you are allergic to other anti-androgen medicines.
- you are taking cisapride or the antihistamines, terfenadine and astemizole.
- you are a woman.

Check with your doctor if you:

- have liver problems. It may not be safe for you to take COSUDEX if you have problems with your liver.
- 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. You may also need additional monitoring (eg ECG and/or blood tests).

- diabetes, as you may need further blood glucose monitoring
- have any other medical conditions
- take any medicines for any other condition
- have allergies to medicines or 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take COSUDEX if you are a woman.

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.

Children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with COSUDEX and affect how it works.

Tell your doctor if you are taking:

- cisapride
- the antihistamines terfenadine and astemizole
- 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
- ciclosporin
- medicines used to treat high cholesterol
- calcium channel blockers
- carbamazepine
- quinidine
- antiviral medicines for HIV infection

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COSUDEX.

4. How do I take COSUDEX?

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.

Follow the directions given to you by your doctor or pharmacist carefully, they may differ from the information contained in this leaflet.

When to take COSUDEX

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 COSUDEX

Continue taking COSUDEX for as long as your doctor or pharmacist tells you.

If you forget to take COSUDEX

COSUDEX should be used regularly at the same time each day. If you miss your dose at the usual time, 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 for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

If you use too much COSUDEX

If you think that you have used too much COSUDEX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using COSUDEX?

Things you should do

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

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.

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.

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

Things you should 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.

- Do not take COSUDEX if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how COSUDEX affects you.

Some patients may feel dizzy or weak.

Looking after your medicine

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 where the temperature stays below 30°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Blood and blood vessel related • dizziness when exercising and looking pale (symptoms of low red blood cells - anaemia) • hot flushes or sweating **Nervous system related** • dizziness or light-headedness • sleepiness **Gut and appetite related** • stomach / abdominal pain	**Speak to your doctor if you have any of these very common side effects and they worry you.**

Less serious side effects	What to do
• constipation • nausea • loss of appetite • indigestion • flatulence (wind) • weight increase **Breast and sex organ/ sex related** • breast tenderness or changes in breast size • decrease in your sexual drive (libido) • inability to get or maintain an erection (impotence / erectile dysfunction) **Mood related** • depression **Skin and hair related** • increased hairiness or hair loss • itching or dry skin, rashes **Other** • unusual tiredness or weakness	

Less serious side effects	What to do
• swelling of parts of the body including hands, feet or ankles	

Serious side effects

Serious side effects	What to do
Heart related • chest pain, signs of a heart attack (such as pressure, tightness or pain in the chest and arms which may spread to the neck, jaw or back, nausea, indigestion or heartburn, cold sweat, fatigue, and/or light-headedness or sudden dizziness) or signs of cardiac failure (such as waking up at night with shortness of breath, difficulty with physical activity, feeling weak or tired, heart palpitations, swelling in your legs, ankles and feet (oedema), swelling or bloating in	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
your abdomen/stomach, dizziness/fainting) **Liver, kidney or bladder related** • yellowing of the skin or eyes (jaundice). These may be symptoms of liver damage. • blood in the urine/dark coloured urine. This may also be a symptom of liver damage. • Other symptoms of liver damage (such as swollen and/or painful abdomen/stomach, feeling tired, 'brain fog', nausea or vomiting, rash, fever, weight loss or loss of appetite) **Immune system related** rash, hives or severe itching of the skin or swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing (allergy / hypersensitivity)	

Serious side effects	What to do
Lung related • serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever. These may be symptoms of inflammation of the lungs known as 'interstitial lung disease' **Blood test related** • excessive thirst with weight loss and/or frequent urination. These may be symptoms of high blood glucose	

Some side effects may be found when your doctor does blood tests (eg low red blood cells (anaemia), high blood glucose (may indicate diabetes or loss of glycaemic control in patients with diabetes), liver function tests) or other tests (eg ECG for heart function) from time to time to check your progress.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What COSUDEX contains

Active ingredient (main ingredient)	bicalutamide
Other ingredients (inactive ingredients)	• lactose monohydrate • sodium starch glycolate • povidone • magnesium stearate (E572) • hypromellose • macrogol 300 • titanium dioxide (E171)

Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

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 (Aust R 54639).

Who distributes COSUDEX

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone:- 1800 805 342

This leaflet was prepared July 2026

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