

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking COSAMIDE 50?

COSAMIDE 50 contains the active ingredient bicalutamide. COSAMIDE 50 is used in combination with other medicines to treat advanced prostate cancer.

For more information, see Section [1. Why am I taking COSAMIDE 50?](#) in the full CMI.

2. What should I know before I take COSAMIDE 50?

Do not use if you have ever had an allergic reaction to COSAMIDE 50 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 take COSAMIDE 50?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COSAMIDE 50 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 take COSAMIDE 50?

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

More instructions can be found in Section [4. How do I take COSAMIDE 50?](#) in the full CMI.

5. What should I know while taking COSAMIDE 50?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking COSAMIDE 50. • Be sure to keep all your appointments with your doctor so your progress can be checked. Use adequate contraception while you are taking COSAMIDE 50 and for at least 130 days after you have stopped taking COSAMIDE 50.
Things you should not do	• Do not take COSAMIDE 50 if you are a woman. Do not give COSAMIDE 50 to anyone else, even if they have the same condition as you. • Do not take COSAMIDE 50 to treat any other complaints unless your doctor tells you to. • Do not stop taking COSAMIDE 50, or lower the dosage, without checking with your doctor.
Driving or using machines	• Be careful driving or operating machinery until you know how COSAMIDE 50 affects you.
Looking after your medicine	• Keep your COSAMIDE 50 tablets in the blister pack until it is time to take them. • Keep your tablets in a cool, dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking COSAMIDE 50?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, some can be minor and temporary. However, some side effects may be serious. Tell your doctor as soon as possible if you notice frequent urination, shortness of breath and dizziness when exercising and looking pale (anaemia), excessive thirst with weight loss, and passing large amounts of urine. Tell your doctor immediately or go to nearest hospital if you have 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, 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.

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.

COSAMIDE® 50

Active ingredient(s): *bicalutamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking COSAMIDE 50. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking COSAMIDE 50.**

Where to find information in this leaflet:

1. [Why am I taking COSAMIDE 50?](#)
2. [What should I know before I take COSAMIDE 50?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take COSAMIDE 50?](#)
5. [What should I know while taking COSAMIDE 50?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking COSAMIDE 50?

COSAMIDE 50 contains the active ingredient bicalutamide. COSAMIDE 50 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. COSAMIDE 50 interferes with some of the actions of these hormones.

COSAMIDE 50 is used to in combination with other medicines to treat advanced prostate cancer.

COSAMIDE 50 should only be taken by men.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

You doctor may have prescribed it for another reason.

COSAMIDE 50 is not addictive.

2. What should I know before I take COSAMIDE 50?

Warnings

Do not take COSAMIDE 50 if:

- you have an allergy to:
 - o any medicine containing bicalutamide
 - o any of the ingredients listed at the end of this leaflet
 - o any other anti-androgen medicine.Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.Always check the ingredients to make sure you can use this medicine.

- you are taking cisapride or the antihistamines, terfenadine and astemizole.
- you are a woman. Women are not normally treated with COSAMIDE 50.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have liver problems
It may not be safe for you to take COSAMIDE 50 if you have problems with your liver.
- have allergies to medicines or substances such as foods, preservatives or dyes.

If you are not sure whether you should start taking this medicine, talk to your doctor.

If you have not told your doctor about any of the above, tell him/her before you start taking COSAMIDE 50.

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 COSAMIDE 50 if you are a woman.

COSAMIDE 50 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 COSAMIDE 50 may affect your sperm, effective contraception must be used by you and/or your partner while you are taking COSAMIDE 50 and for at least 130 days after you have stopped taking COSAMIDE 50.

Children

Do not give COSAMIDE 50 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 COSAMIDE 50 and affect how it works. These include:

Tell your doctor if you are taking:

- cisapride
- the antihistamines terfenadine and astemizole
- medicines used to prevent blood clots, especially warfarin
- midazolam

- ciclosporin
- calcium channel blockers, medicines used to treat high blood pressure
- carbamazepine
- quinidine
- antiviral medicines for HIV infection
- cimetidine
- ketoconazole

These medicines may be affected by COSAMIDE 50 or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COSAMIDE 50.

4. How do I take COSAMIDE 50?

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

- The usual adult dose is one 50 mg tablet taken each day.

How to take COSAMIDE 50

- Swallow your COSAMIDE 50 tablet whole with a glass of water.

When to take COSAMIDE 50

- **Take COSAMIDE 50 at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

- COSAMIDE 50 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 COSAMIDE 50 before, with or after food.

How long to take COSAMIDE 50 for

- Continue taking COSAMIDE 50 for as long as your doctor or pharmacist tells you.

If you forget to take COSAMIDE 50

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.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

If you have taken too much COSAMIDE 50

If you think that you or anyone else has taken too much COSAMIDE 50, urgent medical attention maybe needed.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, 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 taking COSAMIDE 50?

Things you should do

- Keep all of your doctor's appointments so your progress can be checked.
- Remind any doctor, dentist or pharmacist you visit that you are using COSAMIDE 50.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking COSAMIDE 50.
- If you go into hospital, please let the medical staff know you are taking COSAMIDE 50.

Things you must not do

- Do not give COSAMIDE 50 to anyone else, even if they have the same condition as you.
- Do not take COSAMIDE 50 to treat any other complaints unless your doctor tells you to.
- Do not stop taking COSAMIDE 50 or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how COSAMIDE 50 affects you.

Some patients may feel dizzy or weak.

Looking after your medicine

- Keep your COSAMIDE 50 tablets in the blister pack until it is time to take them.
- If you take COSAMIDE 50 out of the blister, it will not keep well.
- Keep it where the temperature stays below 25°C.

Follow the instructions in 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.

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.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COSAMIDE 50.

This medicine helps most people with prostate cancer, but it may have unwanted side effects in some people.

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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• 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.	Speak to your doctor or pharmacist if you have any of these very common side effects and they worry you.

Serious side effects

Serious side effects	What to do
• frequent urination	Tell your doctor as soon as

Serious side effects	What to do
• shortness of breath and dizziness when exercising and looking pale (anaemia) • excessive thirst with weight loss, and passing large amounts of urine.	possible if you notice these serious side effects
• 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	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

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 COSAMIDE 50 contains

Active ingredient (main ingredient)	Bicalutamide 50 mg per tablet
Other ingredients (inactive ingredients)	• lactose monohydrate • povidone • sodium starch glycollate type A • magnesium stearate • hypromellose • macrogol 400 • titanium dioxide.
Potential allergens	lactose

The tablet do not contain sucrose, gluten, tartrazine or any other azo dyes.

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

What COSAMIDE 50 looks like

COSAMIDE 50 tablets are white to off white round, biconvex, film-coated tablets debossed "B 50" on one side and plain on the other side (AUST R 162829).

Each pack contains 28 tablets.

Who distributes COSAMIDE 50

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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COSAMIDE® is a Viatris company trade mark

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