

COSAMIDE® 50

bicalutamide

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about COSAMIDE 50.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking COSAMIDE 50 against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What COSAMIDE 50 is used for

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

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 to grow. COSAMIDE 50 interferes with some of the actions of these hormones.

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.

Your doctor may have prescribed it for another reason.

COSAMIDE 50 is available only with a doctor's prescription.

COSAMIDE 50 is not addictive.

Before you take COSAMIDE 50

When you must not take it

Do not take COSAMIDE 50 if you are a woman.

Women are not normally treated with COSAMIDE 50.

Do not take COSAMIDE 50 if you have an allergy to:

- any medicine containing bicalutamide
- any of the ingredients listed at the end of this leaflet
- any other anti-androgen medicine.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; swelling

of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give COSAMIDE 50 to children.

There is no experience of its use in children.

Do not take COSAMIDE 50 if you are taking cisapride or the antihistamines, terfenadine and astemizole.

Do not take this medicine after the expiry date printed on the pack 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.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell 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.

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

Taking other medicines

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

Some medicines and COSAMIDE 50 may interfere with each other. These include:

- cisapride
- the antihistamines terfenadine and astemizole
- medicines used to prevent blood clots, especially warfarin
- midazolam
- ciclosporin
- medicines used to treat high cholesterol
- 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.

How to 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 it

Swallow the tablet whole with a glass of water.

When to take it

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 without food.

How long to take it

Continue taking COSAMIDE 50 for as long as your doctor tells you to.

If you forget to take it

If it less than 12 hours before 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 take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident

and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much COSAMIDE 50. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking COSAMIDE 50

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking COSAMIDE 50.

Tell any other doctors, dentists and pharmacists who treat you that you are taking COSAMIDE 50.

If you go into hospital, let the medical staff know you are taking COSAMIDE 50.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use COSAMIDE 50 to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dose without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how COSAMIDE 50 affects you.

Some people 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 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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

You may not experience any of them.

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

Tell your doctor or pharmacist 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.

The above list includes the more common side effects of COSAMIDE 50.

Tell your doctor as soon as possible 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.

The above list includes serious side effects which may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the 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.

The above list includes very 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.

Other side effects not listed above may also occur in some people.

After taking COSAMIDE 50

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store COSAMIDE 50 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

COSAMIDE 50 50 mg tablets are white round, biconvex, film-coated tablets, debossed "B 50" on one side and plain on the other side.

Each pack contains 28 tablets.

Ingredients

Each COSAMIDE 50 tablet contains 50 mg of bicalutamide as the active ingredient.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- povidone
- sodium starch glycollate type A
- magnesium stearate

- hypromellose
- macrogol 400
- titanium dioxide.

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

Sponsor

COSAMIDE 50 is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: 1800 274 276

www.viatris.com.au

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COSAMIDE is a Viatris company trade mark

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