

ZOLACOS® CP

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 ZOLACOS CP?

ZOLACOS CP contains the active ingredient goserelin and bicalutamide. ZOLACOS CP is used to treat advanced prostate cancer in men. It is not a cure for prostate cancer. Bicalutamide tablets can also be used to treat disease flare associated with previous goserelin therapy.

For more information, see Section [1. Why am I using ZOLACOS CP?](#) in the full CMI.

2. What should I know before I use ZOLACOS CP?

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

3. What if I am taking other medicines?

Some medicines may interfere with ZOLACOS CP 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 ZOLACOS CP?

- A ZOLADEX implant will be injected under the skin of your stomach every 28 days for the 3.6 mg strength, or once every 3 months for the 10.8 mg strength.
- One 50 mg tablet of COSUDEX is then taken each day for one or three months, as considered appropriate by your doctor.

More instructions can be found in Section [4. How do I use ZOLACOS CP ?](#) in the full CMI.

5. What should I know while using ZOLACOS CP?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using ZOLACOS CP.● Keep all your appointments with your doctor so your progress can be checked.
Things you should not do	<ul style="list-style-type: none">● Do not give ZOLACOS CP to anyone else, even if they have the same condition as you.● Do not use ZOLACOS CP to treat any other complaints unless your doctor tells you to.● Do not stop taking ZOLACOS CP, or change the dosage, without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">● Be careful driving or operating machinery until you know how ZOLACOS CP affects you.

Looking after your medicine

- Keep your tablets in the blister foil until it is time to take them.
- Keep the implant in its foil packaging until it is time for administration by your doctor.
- Keep the packaging in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using ZOLACOS CP?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor immediately 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 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 and 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.

ZOLACOS® CP

Active ingredients: bicalutamide and goserelin

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZOLACOS CP. **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 ZOLACOS CP.**

Where to find information in this leaflet:

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

1. Why am I using ZOLACOS CP?

ZOLACOS CP contains the active ingredient goserelin and bicalutamide. ZOLACOS CP is a combination pack consisting of an anti-androgen (COSUDEX) medicine and a Luteinising Hormone Releasing Hormone (LHRH) agonist (ZOLADEX). Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens

may help the cancer cells to grow. LHRH agonists reduce the level of testosterone in men. ZOLACOS CP interferes with some of the actions of these hormones.

ZOLACOS CP is used to treat advanced prostate cancer in men. It is not a cure for prostate cancer. Bicalutamide tablets can also be used to treat disease flare associated with previous goserelin therapy.

ZOLACOS CP should only be taken by men.

2. What should I know before I use ZOLACOS CP?

Warnings

Do not use ZOLACOS CP if:

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

Symptoms of an allergic reaction may include:

- skin rash
- hay fever

- difficulty breathing
- feeling faint

Check with your doctor if 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 ZOLACOS CP.
- have liver problems. It may not be safe for you to use ZOLACOS CP if you have problems with your liver.
- take any medicines for any other condition

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

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

It is also unlikely that you can father a child while using ZOLACOS CP, but you must use your normal contraceptive method to make sure.

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 ZOLACOS CP and affect how it works.

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

- cisapride (see Warnings)
- the antihistamines terfenadine and astemizole (see Warnings)
- medicines used to prevent blood clots, especially warfarin as ZOLACOS CP may reduce their effectiveness which may lead to bleeding and you therefore may need 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 ZOLACOS CP.

4. How do I use ZOLACOS CP?

How much to take

- A ZOLADEX implant will be injected under the skin of your stomach every 28 days for the 3.6 mg, or once every 3 months for the 10.8 mg strength.
- One 50 mg tablet of COSUDEX is then taken each day for one or three months, as considered appropriate by your doctor.
- **Swallow your tablet whole with a full glass of water.**

When to take ZOLACOS CP

- The implant will be administered once a month or once every three months by your doctor.
- **Take the tablets at about the same time each day.**
- It does not matter if you take the tablets before, with or after food.

How long to take ZOLACOS CP

- Your doctor will tell you how long you will need to be given ZOLACOS CP.

If you forget to use ZOLACOS CP

COSUDEX should be used regularly at the same time each day. If you miss taking a tablet, 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, 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 use too much ZOLACOS CP

If you think that you have used too much ZOLACOS CP, 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 ZOLACOS CP?

Things you should do

- **Be sure to keep all your appointments with your doctor so your progress can be checked.** This is to ensure that your hormone levels will not rise and your illness will not get worse.
- **If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ZOLACOS CP.**
- If you go into hospital, please let the medical staff know you are taking ZOLACOS CP.

Remind any doctor, dentist or pharmacist you visit that you are using ZOLACOS CP.

Things you should not do

- **Do not give ZOLACOS CP to anyone else, even if they have the same condition as you.**
- **Do not use ZOLACOS CP to treat any other complaints unless your doctor tells you to.**
- **Do not stop taking ZOLACOS CP, or change the dosage, without checking with your doctor.**
- **Do not use ZOLACOS CP 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 ZOLACOS CP affects you.

Some patients may feel dizzy or weak.

Looking after your medicine

- **Keep your tablets in the blister foil until it is time to take them.** If you take the tablets out of the blister foil, they will not keep well.
- **Keep the implant in its foil packaging until it is time for administration by your doctor.**
- **Keep the packaging in a cool dry place 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.

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.

You may experience the following side effects:

Very common (may affect more than 1 in 10 people)	What to do
<ul style="list-style-type: none">• hot flushes or sweating• breast tenderness or changes in breast size• stomach pain or indigestion• nausea or vomiting• diarrhoea or constipation• unusual tiredness or weakness• dizziness or light-headedness• changes in blood pressure• headache• chills	Speak to your doctor if you have any of these very common side effects and they worry you.

<p>Very common (may affect more than 1 in 10 people)</p>	<p>What to do</p>
<ul style="list-style-type: none"> ● tingling in fingers or toes ● decrease in your sexual drive ● inability to get or maintain an erection ● your testicles getting smaller 	

<p>Common (may affect up to 1 in 10 people)</p>	<p>What to do</p>
<ul style="list-style-type: none"> ● itching or dry skin, rashes ● increased hairiness or hair loss ● flatulence (wind) ● dry mouth ● loss of appetite or weight changes ● depression ● difficulty sleeping ● pelvic pain ● painful joints ● trouble passing urine or experience lower back pain 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● 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● dizziness when exercising and looking pale (anaemia)● frequent urination	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● excessive thirst with weight loss, and passing large amounts of urine <p>Tell your doctor immediately if any of these things happen while you are using ZOLACOS CP:</p> <ul style="list-style-type: none"> ● have trouble passing urine ● feel weak in the arms or legs ● feel numb in the arms or legs ● have pain in the kidneys ● have pain in the bones or backbone <p>These may mean that the cancer is growing.</p> <p>If you have a tumour in your pituitary gland, ZOLACOS CP may make the tumour bleed or collapse. This is very rare but causes severe headaches, sickness, loss of eyesight and unconsciousness.</p>	

ZOLACOS CP lowers the amount of sex hormones in your body so your sex drive will probably be reduced.

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 ZOLACOS CP contains

Active ingredient (main ingredient)	bicalutamide and goserelin (as the acetate)
Other ingredients	COSUDEX contains:

(inactive ingredients)	<ul style="list-style-type: none"> ● lactose monohydrate ● sodium starch glycolate ● povidone ● magnesium stearate (E572) ● hypromellose ● macrogol 300 ● titanium dioxide (E171) <p>ZOLADEx contains:</p> <ul style="list-style-type: none"> ● polyglactin
Potential allergens	lactose

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

What ZOLACOS CP looks like

ZOLACOS CP contains a syringe with a small pellet containing goserelin and is about the size of a grain of rice. It can be seen in the "window" halfway up the syringe and is white or cream coloured.

The tablets are packaged in a blister strip and are white, round film-coated tablets. One side of the tablet is marked CDX 50 and the other side has an arrow shape.

The tablets are packed in blister foils of 28 tablets.

ZOLACOS CP is available in three different combinations:

- 1 x Zoladex 3.6 mg implant syringe + 28 (1 month) tablets Cosudex 50 mg (Aust R 125685).
- 1 x Zoladex 10.8 mg implant syringe + 28 (1 month) tablets Cosudex 50 mg (Aust R 125687).
- 1 x Zoladex 10.8 mg implant syringe + 84 (3 month) tablets Cosudex 50 mg (Aust R 125687).

Who distributes ZOLACOS CP

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone:- 1800 805 342

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