

ZOLACOS CP™

bicalutamide & goserelin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about ZOLACOS CP. It does not contain all the information that is known about ZOLACOS CP.

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 ZOLACOS CP 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 ZOLACOS CP is for

ZOLACOS CP combination therapy is the brand name for packs containing ZOLADEX (goserelin) 3.6mg or 10.8mg subcutaneous implant plus COSUDEX (bicalutamide) 50mg tablets.

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 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 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.

ZOLACOS CP is not addictive.

Before you use ZOLACOS CP

When you must not use it

Do not use ZOLACOS CP if you are a woman or a child.

Do not use ZOLACOS CP if you are allergic to bicalutamide, goserelin or any of the other ingredients in ZOLACOS CP.

Do not use ZOLACOS CP if you are taking cisapride or the antihistamines, terfenadine and astemizole.

Do not use ZOLACOS CP after the use by (expiry) date printed on the pack.

It may have no effect at all or an unexpected effect if you use it after the expiry date.

Do not use ZOLACOS CP 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 or goserelin, the active ingredients in ZOLACOS CP
- any of the other ingredients of ZOLACOS CP listed at the end of this leaflet
- other anti-androgen medicines
- other LHRH agonists
- 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 use ZOLACOS CP 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 ZOLACOS.

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 ZOLACOS CP 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 ZOLACOS CP works or ZOLACOS CP 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 use any ZOLACOS CP.

Being given ZOLACOS CP

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

They may differ from the information contained in this leaflet.

How much to take

A ZOLADEX implant will be injected under the skin of your

stomach every 28 days for the 3.6mg strength, or once every 3 months for the 10.8mg strength.

One (x1) 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 it

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 it

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

If you forget to take it

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 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 many tablets. 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.

This is to ensure that your hormone levels will not rise and your illness will not get worse.

Tell your doctor immediately if any of these things happen while you are using ZOLACOS CP

- 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

These may mean that the cancer is growing.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking ZOLACOS CP.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking ZOLACOS CP.

ZOLACOS 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 ZOLACOS and for at least 130 days after you have stopped taking ZOLACOS.

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

Things you must 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.

Things to be careful of

Be careful driving or operating machinery until you know how ZOLACOS CP 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 ZOLACOS CP.

ZOLACOS CP helps people with advanced 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 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
- changes in blood pressure
- difficulty sleeping

- headache
- pelvic pain
- painful joints
- chills
- tingling in fingers or toes
- decrease in your sexual drive
- inability to get or maintain an erection
- trouble passing urine or experience lower back pain
- your testicles getting smaller

ZOLACOS CP 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 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.

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 ZOLACOS CP.

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

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.

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.

After using ZOLACOS CP

Storage

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.

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. Your doctor will dispose of the syringe appropriately.

Product description

What ZOLACOS CP looks like

ZOLACOS CP is available in three different combinations:

1x Zoladex 3.6mg implant syringe +
28 (1 month) tablets Cosudex 50mg

1x Zoladex 10.8mg implant syringe +
28 (1 month) tablets Cosudex 50mg

1x Zoladex 10.8mg implant syringe +
84 (3 month) tablets Cosudex 50mg

The syringe contains a small pellet containing goserelin and is about the size of a grain of rice. It can be seen in the "window" half way 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.

Ingredients

Each 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)

Each 3.6mg implant syringe contains the active ingredient goserelin 3.6mg (as the acetate) plus polyglactin.

Each 10.8mg implant syringe contains the active ingredient goserelin 10.8mg (as the acetate) plus polyglactin.

ZOLACOS CP does not contain added sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

AstraZeneca Pty Ltd

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This leaflet was prepared on 18 May 2017.

Australian Registration Numbers

ZOLACOS CP 3.6/50

AUST R 125685

ZOLACOS CP 10.8/50

AUST R 125687

Doc ID-002699670 v6.0