
Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Calutex. It does not contain all the information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking Calutex against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.
You may need to read it again.

What Calutex is used for

Calutex is used in combination with other medicines to treat advanced prostate cancer. Calutex contains bicalutamide as the active ingredient. Bicalutamide belongs to a group of medicines called anti-androgens.

Androgens such as testosterone are natural male sex hormones. In some types of prostate cancer, androgens may help the cancer cells to grow. Calutex interferes with some of the actions of these hormones.

Calutex should only be taken by men.

Follow all directions given to you by your doctor.

They may differ from the information in this leaflet.

Ask your doctor if you have any questions about why it has been prescribed for you.
Your doctor may have prescribed this medicine for another reason.

Calutex is only available with a doctor's prescription.

It is not addictive.

Before you take it

When you must not take it

Do not take Calutex if you are a woman.

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

Do not take Calutex if you are allergic to bicalutamide or any of the other tablet ingredients listed at the end of the leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other part of the body; rash, itching or hives on the skin.

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

Do not take Calutex after the use by (expiry) date printed on the pack.
It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take Calutex 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 take it

You must tell your doctor if you have had any allergies to any other anti-androgen medicines, any other medicines or

substances such as foods, preservatives or dyes.

Tell your doctor if you have or have had any liver problems.

It may not be safe for you to take Calutex if you have problems with your liver.

Tell your doctor if you are diabetic.

Your doctor may need to monitor your blood glucose levels whilst taking this medicine.

Tell 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 Calutex.

Tell your doctor or pharmacist if you are taking coumarin anticoagulants.

Taking Calutex with these medicines may increase the risk of bleeding.

Taking other medicines

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

Some medicines may be affected by Calutex or may affect how well it works. These include:

- cisapride
- the antihistamines terfenadine and astemizole
- medicines used to prevent blood clots, especially warfarin
- ketoconazole
- cimetidine
- midazolam
- cyclosporin
- medicines used to treat high cholesterol
- calcium channel blockers
- carbamazepine
- quinidine
- antiviral medicines for HIV infection.

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

How to take it

How much to take

Take your medicine as directed by your doctor.

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

Calutex should be started at the same time as the other medicines you have been given for the treatment of prostate cancer.

This medicine can be taken before, with or after food.

How long to take it

Continue taking Calutex for as long as your doctor tells you.

If you forget to take it

If you miss a dose take it as soon as you remember, as long as it is 12 hours before the next dose is due.

However, 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.

Ask your doctor or pharmacist if you are not sure what to do.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Calutex. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Be sure to keep all your doctor's appointments so your condition can be monitored.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Calutex, especially if you are about to be started on any new medicine.

Calutex 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 Calutex and for at least 130 days after you have stopped taking this medicine.

Things you must not do

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

Do not take Calutex to treat any other complaints unless your doctor tells you to.

Do not stop taking Calutex, or lower the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Calutex 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 Calutex.

Calutex helps most people with advanced prostate cancer but it may have unwanted side effects in a few 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
- depression
- loss of appetite or weight changes
- unusual tiredness or weakness
- dizziness or light-headedness
- headache
- swelling of hands, ankles or feet
- difficulty sleeping
- chills
- pelvic pain
- depression
- decrease in your sexual drive
- inability to get or maintain an erection.

These are common side effects of Calutex.

Tell your doctor immediately if you notice any of the following:

- chest pain
- 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:

- severe 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
- serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever
- shortness of breath, wheezing or trouble breathing.

These are serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep Calutex tablets in the blister foil until it is time to take them.

If you take Calutex out of the blister foil, it will not keep as well.

Keep it 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

If your doctor tells you to stop taking Calutex or you find that the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product Description

What it looks like

Calutex 50 mg are white, biconvex film-coated tablets.

Available in blister packs of 28 tablets.

Ingredients

Active ingredient:

Each tablet contains 50 mg of bicalutamide.

Inactive ingredients:

- lactose monohydrate
- sodium starch glycollate
- povidone
- magnesium stearate
- Opadry complete film coating system white Y-1-1700.

Calutex does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

Australia Registration Number:
AUST R 135858

This leaflet was revised in May 2019.