

# Calutex tablets

## 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 Calutex?

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

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

### 2. What should I know before I use Calutex?

Do not use if you have ever had an allergic reaction to bicalutamide or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions or take any other medicines.**

For more information, see Section [2. What should I know before I use Calutex?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Calutex 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 Calutex?

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

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

### 5. What should I know while using Calutex?

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Calutex.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Do not stop using this medicine or lower the dosage without checking with your doctor.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Calutex affects you.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Keep Calutex tablets in the blister foil until it is time to take them.</li><li>• Keep it in a cool dry place where the temperature stays below 25°C.</li></ul>

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

### 6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

Common side effects include diarrhoea or constipation, nausea, dry mouth, depression, unusual tiredness and itching or dry skin.

Serious side effects include chest pain, breathlessness, yellowing of the skin and difficulty in swallowing.

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.

# Calutex tablets

Active ingredient: *bicalutamide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Calutex. **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 Calutex.**

Where to find information in this leaflet:

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

### 1. Why am I taking Calutex?

Calutex contains the active ingredient bicalutamide. It belongs to a group of medicines called anti-androgens.

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

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.

**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.

### 2. What should I know before I use Calutex?

#### Warnings

**Do not use Calutex if:**

- you are allergic to bicalutamide or any of the ingredients listed at the end of this leaflet.
- you are a woman. Calutex should only be taken by men.
- you are taking cisapride or the antihistamines terfenadine and astemizole.

**Do not give Calutex to children.**

There is no experience of its use in children.

**Check with 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.

- have any other medical conditions such as:

- **liver problems.**  
It may not be safe for you to take Calutex if you have problems with your liver.
- **diabetes.**  
Your doctor may need to monitor your blood glucose levels whilst taking this medicine.
- **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.
- **if you are taking coumarin anticoagulants.**  
Taking Calutex with these medicines may increase the risk of bleeding.

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?](#)

### 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 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.

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

### 4. How do I take Calutex?

#### How much to take

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

- Follow the instructions provided and use Calutex until your doctor tells you to stop.

### When to take Calutex

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

### How to take Calutex

- Swallow the tablet whole with a glass of water.
- This medicine can be taken before, with or after food.

### If you forget to use Calutex

Calutex should be used regularly at the same time each day.

If you miss your dose at the usual time, 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 you missed.

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

### If you use too much Calutex

If you think that you have used too much Calutex, 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 Calutex?

### Things you should do

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

### Things you should 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.**

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Calutex affects you.**

Calutex may cause dizziness or weakness in some people

### Looking after your medicine

- **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.**
- **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.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• hot flushes or sweating</li> <li>• breast tenderness or changes in breast size</li> <li>• itching or dry skin, rashes</li> <li>• increased hairiness or hair loss</li> <li>• stomach pain or indigestion</li> <li>• nausea or vomiting</li> <li>• diarrhoea or constipation</li> <li>• flatulence (wind)</li> <li>• dry mouth</li> <li>• depression</li> <li>• loss of appetite or weight changes</li> <li>• unusual tiredness or weakness</li> <li>• dizziness or light-headedness</li> <li>• headache</li> <li>• swelling of hands, ankles or feet</li> <li>• difficulty sleeping</li> <li>• chills</li> <li>• pelvic pain</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• depression</li> <li>• decrease in your sexual drive</li> <li>• inability to get or maintain an erection.</li> </ul> <p>These are common side effects of Calutex.</p>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• chest pain</li> <li>• shortness of breath and dizziness when exercising and looking pale (anaemia)</li> <li>• excessive thirst with weight loss, and passing large amounts of urine.</li> </ul>	<p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p>
<ul style="list-style-type: none"> <li>• severe chest pain</li> <li>• yellowing of the skin or eyes and dark coloured urine</li> <li>• rash, hives or severe itching of the skin</li> <li>• swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing</li> <li>• serious breathlessness, or sudden worsening of breathlessness, possibly with a cough or fever</li> <li>• shortness of breath, wheezing or trouble breathing.</li> </ul>	<p><b>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.</b></p> <p>You may need urgent medical attention or hospitalisation.</p>

**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](http://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. It is not addictive.

### What Calutex contains

<b>Active ingredient (main ingredient)</b>	Bicalutamide 50 mg/tablet
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• lactose monohydrate</li> <li>• sodium starch glycollate</li> <li>• povidone</li> <li>• magnesium stearate</li> <li>• Opadry complete film coating system white Y-1-1700.</li> </ul>
<b>Potential allergens</b>	Lactose monohydrate

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

### What Calutex looks like

Calutex is a white, biconvex film coated tablet. Available in blister packs of 28 tablets.

Australian Registration Number: AUST R 135858

### Who distributes Calutex

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

This leaflet was prepared in February 2022.