

FLUTAMIN

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 taking FLUTAMIN?

FLUTAMIN contains the active ingredient flutamide. FLUTAMIN is used in combination with medical castration to treat prostate cancer. For more information, see Section [1. Why am I taking FLUTAMIN?](#) in the full CMI.

2. What should I know before I take FLUTAMIN?

Do not take if you have ever had an allergic reaction to flutamide 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 take FLUTAMIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLUTAMIN 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 take FLUTAMIN?

- Take one tablet by mouth three times a day, exactly as directed by your doctor.

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

5. What should I know while taking FLUTAMIN?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking FLUTAMIN.
- Tell your doctor or pharmacist if you are taking any other medicines.
- Tell your doctor or pharmacist that you are taking FLUTAMIN if you

	are about to be started on any new medicines.
Things you should not do	<ul style="list-style-type: none"> • Do not stop taking FLUTAMIN, or change the dose, without checking with your doctor. • Do not use FLUTAMIN to treat any other complaints unless your doctor tells you to. • Do not give FLUTAMIN to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none"> • Make sure you know how you react to FLUTAMIN before you drive a car or operate machinery.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 25°C in a cool dry place away from moisture, heat or sunlight. • Keep your tablets in the pack until it is time to take them.

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

6. Are there any side effects?

Less serious side effects: always feeling hungry, blurred vision, decrease in sexual desire or sexual ability, diarrhoea, difficulty sleeping, drowsiness, feeling fatigued, headaches and feeling dizzy, hot flushes (sudden sweating and feelings of warmth), increased breast size, nausea (feeling sick), rash, vomiting.

Serious side effects: anxiety, bleeding or bruising more than normal, confusion, constant tiredness or “flu-like” symptoms, dark urine (amber or yellow-green urine is not a cause for concern), depression, high blood pressure, itching of the skin, loss of appetite, mood swings, muscle ache or twitching, nausea, nervousness, persistent lack of appetite, shortness of breath, slow healing cuts or infection, tenderness in the right upper stomach, vomiting, yellow eyes or skin.

Very serious side effects: difficult or labored breathing, excessive thirst and urination, heart rhythm disorder, leg cramps, liver damage or brain coma from liver illness, tingling/numbness in hands and/or feet, unusual weight loss or weight gain, swelling of feet or lower legs, yellow discolouration of the skin or eyes due to failure to remove bile. 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.

FLUTAMIN

Active ingredient: *flutamide*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking FLUTAMIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking FLUTAMIN.**

Where to find information in this leaflet:

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

1. Why am I taking FLUTAMIN?

FLUTAMIN contains the active ingredient flutamide. FLUTAMIN is an antiandrogen. Antiandrogens work by blocking the adrenal androgens (male hormones) from reaching the cancer cells.

FLUTAMIN is used in combination with medical castration to treat prostate cancer.

The combination of medical castration and FLUTAMIN, blocks androgens from all sources; this is called maximal androgen blockade.

The Prostate Gland

The prostate gland is a walnut-sized gland that surrounds the upper part of the urethra. The urethra is a tube through which urine and sperm exit through the tip of the penis. The main job of the prostate gland is to produce fluid that nourishes and transports sperm. The gland is vulnerable to two common but unrelated medical problems - enlargement and cancer.

Cancer of the Prostate

Prostate cancer is the most common cancer among Australian men. About 1 in every 10 men will develop the disease in his lifetime. The causes of prostate cancer are unknown but the disease is often responsive to treatment.

Who is at risk?

Prostate cancer is more common in older men; 80% of men who develop prostate cancer are diagnosed when they are over the age of 65. However, some men develop the disease when they are younger.

What is Maximal Androgen Blockade?

Prostate cancer cells need androgens to grow. There are two sources of androgens in your body: the testes and the adrenal glands (small glands that sit on top of your kidneys). Maximal androgen blockade which combines castration and a medicine called an

antiandrogen, is designed to prevent the androgens from both sources reaching and nourishing the cancer cells.

Castration stops the production of testosterone by the testes. Castration can be accomplished either surgically or medically. Surgical castration, called an orchidectomy, is the actual removal of the testes. Medical castration involves taking hormonal drugs known as luteinising hormone-releasing hormone (LHRH) agonists which stop the testes from producing testosterone. Two examples of LHRH agonists are leuprolide and goserelin acetate. LHRH agonists are given as monthly injections.

While castration "shuts off" the production of testosterone by the testes, it does nothing to stop the androgens produced by the adrenal glands from continuing to nourish the cancer cells.

There is no evidence that FLUTAMIN is addictive.

2. What should I know before I take FLUTAMIN?

Warnings

Do not take FLUTAMIN if:

- you are allergic to medicines containing flutamide, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - skin rash, itching or hives

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or shortness of breath

Always check the ingredients to make sure you can take this medicine.

- you have serious liver problems.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.
- you are a woman who is pregnant or breastfeeding. FLUTAMIN is for use by men only.

Check with your doctor if you:

- are allergic to any other medicines, or any foods, dyes or preservatives
- any other medical conditions or health problems.
- are pregnant or breastfeeding
- have liver problems
- have or have had heart disease, a condition called 'long QT syndrome' or a family history of this heart condition
- have diabetes
- have or have had a history of anaemia, a low red blood cell count
- have low bone mineral density (BMD)
- have osteoporosis or a strong family history of osteoporosis or bone fracture
- consume large quantities of alcohol and/or tobacco
- take medicines to treat epilepsy/fits

- take medicines to reduce the activity of your immune system.

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

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 interfere with FLUTAMIN and affect how it works. These include:

- oral anticoagulants such as warfarin, a medicine used to prevent blood clots
- theophylline, used for asthma
- medicines used to treat irregular heart rhythm e.g. quinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide, dronedarone, flecainide, propafenone
- medicines that help correct chemical imbalances in the brain which may cause mental illness or behavioural disturbances e.g. chlorpromazine
- medicines used to treat depression e.g. amitriptyline, nortriptyline

- medicines used to help control pain, e.g. methadone
- medicines which treat infection caused by bacteria e.g. erythromycin, clarithromycin, azithromycin, moxifloxacin
- quinine, an antimalarial
- azole antifungals which prevent growth of fungal and yeast organisms
- medicines that help stop nausea and vomiting e.g. ondansetron
- medicines used in the treatment of asthma e.g. salbutamol.

Your doctor can tell you what to do if you are taking this medicine.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking FLUTAMIN.

4. How do I take FLUTAMIN?

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

- Take one tablet by mouth three times a day, exactly as directed by your doctor.

When to take FLUTAMIN

- Taking FLUTAMIN every eight hours is the best way of making sure the therapy will block the androgens in your body.
- Take one tablet when you first get up, one in the afternoon and one at bedtime.
- FLUTAMIN can be taken with or without food.
- Do not use meals as a reminder to take FLUTAMIN because meals are not normally 8 hours apart.

How to take FLUTAMIN

- Swallow the tablets whole with a full glass of water.

How long to take FLUTAMIN for

- Continue to take FLUTAMIN regularly, for as long as your doctor tells you to.
- Do not stop taking this medicine without first checking with your doctor.

If you forget to take FLUTAMIN

If you forget to take it, ask your doctor or pharmacist for advice.

If it is almost time for 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 tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you take too much FLUTAMIN

If you think that you or anyone else has taken too much FLUTAMIN, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking FLUTAMIN?

Things you should do

- Tell your doctor or pharmacist if you are taking any other medicines.
- Your doctor may want you to have your blood tested occasionally during your therapy.
- Take FLUTAMIN exactly as your doctor has prescribed.

- Tell all doctors, dentists and pharmacists who are treating you that you are taking FLUTAMIN.
- Tell your doctor or pharmacist that you are taking FLUTAMIN if you are about to be started on any new medicines.

Things you should not do

- Do not stop taking FLUTAMIN, or change the dose, without checking with your doctor.
- Do not use FLUTAMIN to treat any other complaints unless your doctor tells you to.
- Do not give FLUTAMIN to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

FLUTAMIN generally does not cause any problems with your ability to drive a car or operate machinery.

However, make sure you know how you react to FLUTAMIN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

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

If you take your tablets outside of the pack they will not keep well.

- Store below 25°C.

Follow the instructions on 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take 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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FLUTAMIN.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by this list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● rash● always feeling hungry● blurred vision● decrease in sexual desire or sexual ability● difficulty sleeping● drowsiness● feeling fatigued● headaches and feeling dizzy● nausea and vomiting <p>Patients receiving a combination of FLUTAMIN plus medical castration may have:</p> <ul style="list-style-type: none">● diarrhoea● hot flushes (sudden sweating and feelings of warmth)	<p>Speak to your doctor if you have any of these less serious side effects.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● increased breast size ● nausea (feeling sick) ● vomiting 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● dark urine (amber or yellow-green urine is not a cause for concern) ● itching of the skin ● nausea, vomiting ● persistent lack of appetite ● yellow eyes or skin ● tenderness in the right upper stomach ● constant tiredness or "flu-like" symptoms <p>The above side effects may indicate liver disorder, which has been reported very rarely with FLUTAMIN.</p> <ul style="list-style-type: none"> ● anxiety ● confusion 	<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"> ● bleeding or bruising more than normal ● depression ● high blood pressure ● loss of appetite ● mood swings ● muscle ache or twitching ● nervousness ● shortness of breath ● slow healing cuts or infection 	

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none"> ● difficult or labored breathing ● excessive thirst and urination ● heart rhythm disorder ● leg cramps, tingling/ numbness in hands and/ or feet ● liver damage or brain coma from liver illness ● unusual weight loss or weight gain 	<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>

Very serious side effects	What to do
<ul style="list-style-type: none"> ● yellow discolouration of the skin or eyes due to failure to remove bile ● swelling of feet or lower legs 	

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.

In general, patients will experience few additional effects when FLUTAMIN therapy is added to medical castration.

The following tips may help if you are experiencing diarrhoea:

- drink plenty of fluids
- cut down on dairy products
- try eating smaller food portions
- eat more carbohydrates

in consultation with your doctor, you may also try taking medication to manage diarrhoea.

Since a variety of medications can cause diarrhoea, it is important to tell your physician about all the medicines you take, including those that are non-prescription.

Any therapy that stops the production of male hormones, such as medical or surgical castration, will affect your sex drive. It is important to remember that the reduction of androgen levels may make erection more difficult. If

you experience problems, please ask your doctor about available treatment options.

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 FLUTAMIN contains

Active ingredient (main ingredient)	flutamide 250 mg per tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● lactose monohydrate● microcrystalline cellulose● maize starch● pregelatinised maize starch

	<ul style="list-style-type: none"> • sodium lauryl sulfate • colloidal anhydrous silica • magnesium stearate
Potential allergens	sulfites and sugars as lactose

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

What FLUTAMIN looks like

FLUTAMIN is a biconvex, round, yellow tablet debossed "FT" breakline "250" on one side and "G" on the reverse (AUST R 65675).

FLUTAMIN is available in packs of 100 tablets.

Who distributes FLUTAMIN

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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