

## FLUTAMIN

*Flutamide*

*250mg tablets*



---

### What is in this leaflet

---

This leaflet answers some common questions about Flutamin.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Flutamin 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 your medicine. You may need to read it again.

---

### What Flutamin is used for

---

Flutamin contains the active ingredient Flutamide, it belongs to a group of medicines called non-steroidal anti-androgen medicines. Flutamin may be used alone or in combination with another medicine (luteinising hormone-releasing hormone [LHRH] agonists) in the treatment of prostate cancer.

The causes of prostate cancer are unknown but the disease is often responsive to treatment. This medicine works by blocking the effects of androgens, male hormones, which prostate cancer cells need to grow.

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

Flutamin is available only with a doctor's prescription.

There is no evidence that Flutamin is addictive.

**Flutamin is suitable for use in men only.** It should not be used in women or children.

---

### Before you take Flutamin

---

#### *When you must not take it*

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 that may cause difficulty in swallowing or breathing, wheezing or shortness of breath.
- **you have a serious liver problem**
- **you are female**  
Flutamin is only for use in males.
- **the expiry date (Exp.) printed on the pack has passed**

- **the packaging shows signs of tampering or the tablets do not look quite right**

If you are not sure whether you should start taking this medicine, talk to your doctor.

### ***Before you start to take it***

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have, or have had any other medical conditions, especially liver problems.**

Your doctor may want to take special care if you have or have had any liver problems.

### ***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 Flutamin, or may affect how well Flutamin works. These include:

- oral anticoagulant medicines, used to prevent blood clots, such as warfarin.
- theophylline, a medicine used to help breathing problems such as asthma or other lung disease.
- other hormonal therapy including medicines containing androgens and oestrogens.

Your doctor can tell you what to do if you are taking any of the above medicines.

**If you are not sure whether or not you are taking any of the above medicines, check with your doctor or pharmacist.**

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

---

## **How to take Flutamin**

---

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

**If you do not understand the instructions on the pack, ask your doctor or pharmacist.**

### ***How much to take***

The usual dose is one tablet three times a day (one tablet approximately every 8 hours).

### ***How to take Flutamin***

Swallow the tablets with a glass of water.

### ***When to take Flutamin***

**Take Flutamin every 8 hours.**

Flutamin works best when the doses are spaced evenly throughout the day.

### ***If you forget to take Flutamin***

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 the missed dose 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 are not sure what to do, ask your doctor or pharmacist.

### ***How long to take Flutamin for***

To properly control your condition, Flutamin must be taken every day.

**Keep taking Flutamin for as long as your doctor recommends.**

How long to take Flutamin for depends on your response to treatment.

---

## **While you are taking Flutamin**

---

### ***Things you must do***

**Before starting any new medicine, tell your doctor or pharmacist that you are taking Flutamin.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Flutamin.**

**Visit your doctor regularly for check-ups.**

Your doctor may ask you to have blood tests to check your liver, especially during the first 4 months of treatment.

**If you need to have any other blood tests, tell your doctor that you are taking Flutamin.**

Flutamin may affect the results of some tests.

### ***Things you must not do***

Do not stop taking Flutamin, or change the dose, without checking with your doctor.

Do not use Flutamin to treat any other conditions unless your doctor tells you to.

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

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how Flutamin affects you.**

Flutamin may cause dizziness and tiredness in some people.

---

## **Side effects**

---

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

Flutamin helps most people with 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.

Your doctor may lower your Flutamin dose to reduce any side effects that you may experience during treatment.

**Do not be alarmed at this list of side effects, you may not experience any of them.**

Ask your doctor or pharmacist to answer any questions you may have.

**Tell your doctor if you notice any of the following and they worry you:**

- decrease in sex drive or ability
- nausea (feeling sick), vomiting, change in appetite
- diarrhoea or constipation
- breast enlargement and/or tenderness of the breast (sometimes with secretion from the breast)
- headache, dizziness
- tiredness, difficulty sleeping
- feeling generally unwell.

The above list includes the more mild and/or common side effects of Flutamin.

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

- bleeding or bruising more easily than normal
- dizziness, tiredness, headaches, being short of breath when exercising and looking pale
- swelling of the hands, ankles or feet
- increased sensitivity of the skin to the sun
- signs of liver problems such as
  - yellowing of the eyes or skin (jaundice)
  - itching of the skin
  - dark urine (amber or yellow-green urine is not a cause for concern)
  - continued loss of appetite or weight loss
  - tenderness in the right upper stomach
  - flu-like symptoms

The above list includes serious side effects, which may require medical attention.

**Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**

- swelling of the face, mouth, lips, throat or neck, difficulty swallowing or shortness of breath
- hives or any type of skin rash or peeling of the skin

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Flutamin. You may need urgent medical attention or hospitalisation.

**This is not a complete list of all the possible side effects.**

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of side effects. You may not experience any of them.

---

## **After using Flutamin**

---

### **Storage**

**Keep Flutamin 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.

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

If you take the tablets out of the pack, they may not keep as well.

**Keep Flutamin in a cool dry place, away from direct light where the temperature stays below 30 °C.**

**Do not store Flutamin or any other medicine in the bathroom or near a sink.**

**Do not leave Flutamin in the car or on window sills.**

Heat and dampness can destroy some medicines.

## ***Disposal***

If your doctor tells you to stop taking Flutamin, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

---

## **In case of overdose**

You should only take the number of tablets that you have been told.

**Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think you, or anyone else may have taken too much FLUTAMIN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.** Take the container of FLUTAMIN with you if you can.

Keep telephone numbers for these places handy.

---

## **Product description**

### ***What it looks like***

Flutamin is a yellow, 12mm round, biconvex, standard concave tablet debossed with FT above the score and 250 below the score on one side of the tablet and G on the other side.

### ***Ingredients***

The active ingredient in Flutamin is flutamide. Each Flutamin tablet contains 250 mg of flutamide.

The tablets also contain:

- lactose
- microcrystalline cellulose
- maize starch
- pregelatinised maize starch
- sodium lauryl sulfate
- colloidal silicon dioxide
- magnesium stearate.

Flutamin tablets are gluten free.

---

## **If you want to know more**

Should you have any questions regarding this product, please contact your doctor or pharmacist.

### ***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd,  
PO Box 11183,  
Ellerslie,  
Auckland.

Phone: (09) 579 2792

### ***Date of information***

12 May 2009  
(Based on datasheet 12 May 2009)