

## FLUTAMIN

### *Flutamide 250 mg Tablets*



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## What is in this leaflet

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Please read this leaflet carefully before you start taking Flutamin.

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 the medicine.** You may need to read it again.

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## What Flutamin is used for

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Flutamin may be used alone or in combination with another medicine (luteinising hormone-releasing hormone [LHRH] agonists) in the treatment of prostate cancer.

Flutamin contains the active ingredient Flutamide. It belongs to a group of medicines called non-steroidal anti-androgen medicines.

The causes of prostate cancer are unknown but the disease is often responsive to treatment.

Flutamin works by blocking the effects of androgens, which are male hormones that prostate cancer cells need for growth.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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. Flutamin should NOT be used in women or children.**

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## Before you take Flutamin

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### When you must not take it:

Do not take Flutamin if:

- you have a serious liver problem
- you are female

### Do not take Flutamin if you have an allergy to:

- any medicine containing Flutamide
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not give this medicine to children.** This medicine is for adult males only.

**Do not give this medicine to a female.** This medicine is for adult males only.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.** If it has expired or is damaged,

return it to your pharmacist for disposal.

**If you are not sure whether you should take this medicine, talk to your doctor.**

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

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

**Tell your doctor if you have or have had any of the following medical conditions:**

- high blood pressure
- heart problems
- liver problems
- diabetes
- anaemia
- osteoporosis
- drink alcohol or smoke

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

### ***Taking other medicines***

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

Some medicines and Flutamin may interfere with each other. These include:

- oral anticoagulant medicines, such as warfarin, which are used to prevent blood clots
- theophylline, a medicine used to help prevent breathing problems like asthma
- other hormonal therapy including medicines containing androgens or oestrogens
- antiarrhythmia medicines, such as amiodarone, flecainide, sotalol, quinidine, disopyramide,

dofetilide, ibutilide, dronedarone or propafenone which are used to treat heart problems

- antidepressants, such as amitriptyline or nortriptyline
- antibiotics, such as erythromycin, clarithromycin, azithromycin, or moxifloxacin
- antimalarial medicines, such as quinine
- opioid medication, such as methadone
- non-steroidal anti-inflammatory (NSAIDs)
- paracetamol
- medicines to treat nausea, such as ondansetron
- asthma reliever medication, such as salbutamol
- chlorpromazine, a medicine to use in the treatment of psychosis.
- medicines used to treat fungal infections

These medicines may be affected by Flutamin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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## How to take Flutamin

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**Take Flutamin exactly as prescribed by your doctor.**

**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 box, ask your doctor or pharmacist for help.**

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

The usual dose for Flutamin is one tablet by mouth three times daily (one tablet approximately every 8 hours).

### ***How to take it***

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

### ***When to take it***

**Take Flutamin approximately every 8 hours.** Flutamin works best to block the androgens in your body when doses are spaced evenly throughout the day.

Take one tablet when you first get up, one in the afternoon and one at bedtime.

Do not use meals as a reminder to take Flutamin as meals are not normally 8 hours apart.

It does not matter if you take this medicine before or after food.

### ***How long to take it***

**Continue taking your medicine regularly every day for as long as your doctor tells you.**

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

**Do not stop taking this medicine without checking with your doctor first.**

### ***If you forget to take it***

**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 medicine as you would normally.**

**Do not take a double dose to make up for the dose that you missed.** This may increase the chance of you getting an unwanted side effect.

**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 advice.

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

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## While you are using Flutamin

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

**Take Flutamin exactly as your doctor has prescribed.**

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may want you to have blood tests from time to time while you are on Flutamin to make sure the medicine is working and to prevent unwanted side effects.

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

**Tell your doctor or pharmacist if you are taking any other medicines.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.** It may affect other medicines used during surgery.

**Before starting any new medicines, remind your doctor and pharmacist that you are taking Flutamin.**

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

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

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

**Do not stop taking your medicine or change the dose without checking with your doctor.**

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

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

This medicine may cause drowsiness, dizziness, confusion, tiredness or blurred vision in some people. If you have any of these symptoms, do not drive, operate

machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, drowsiness, dizziness, confusion, tiredness or blurred vision may be worse.

**If you take too much (overdose)**

**Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that 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.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Flutamin.** This medicine helps most people with 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 attention if you get some of the side effects.**

**Do not be alarmed by the following lists 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 or pharmacist if you notice any of the following and they worry you:

- diarrhoea or constipation
- nausea (feeling sick) or vomiting
- hot flushes (sudden sweating and feelings of warmth)
- 
- decreased sexual drive or ability

- headache
- dizziness
- feeling generally unwell
- drowsiness
- difficulty sleeping
- tiredness

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

- increased breast size or breast tenderness or breast secretions
- increased or decreased appetite
- excessive thirst or urination
- unusual weight gain or loss
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- confusion
- skin looking pale
- slow healing cuts or infection
- injection site irritation or rash, or other skin problems
- muscle ache (malaise) or twitch
- blurred vision
- nervousness, feeling anxious, depressed, or other mood changes
- shingles or skin problems
- bleeding or bruising more than normal
- shortness of breath or difficulty breathing
- swelling of hands, feet or legs
- increased sensitivity of the skin to the sun
- breast lumps or pain
- skin ulcers or redness of skin

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

Other problems such as high blood sugar levels and low sperm counts have been reported but these are rare.

**Tell your doctor immediately if you notice any of the following symptoms. These may indicate liver disorder, which has been reported very rarely with Flutamin.**

- yellow discolouration of the eyes or skin (jaundice)
- itching of the skin
- dark urine (amber or yellow-green urine is not a cause for concern)
- persistent loss of appetite
- tenderness in the upper right stomach
- constant tiredness or “flu-like” symptoms

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**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, mouth, lips, tongue or throat which may cause difficulty in swallowing or breathing
- chest pain
- severe and sudden onset of rash, itchiness, hives (itchy swellings on the skin)
- blistering (that may or may not have fluid) or peeling of skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

**This is not a complete list of side effects.** Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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

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## After using Flutamin

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### Storage

**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 well.

**Keep your tablets in a cool, dry place where the temperature stays below 30°C.** Store the tablets away from direct sunlight and protect from light.

Do not store Flutamin or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

**Keep medicines where children cannot reach them.**

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

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

Telephone: 0800 579 811

## ***Date of Information***

24 June 2020  
(Based on datasheet dated  
24 June 2020)

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## **Product description**

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

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

These tablets are packed in blisters.

### ***Ingredients***

Flutamin contains 250 mg of Flutamide as the active ingredient.

It also contains:

- lactose monohydrate
- maize starch
- pre-gelatinised maize starch
- microcrystalline cellulose
- sodium lauryl sulphate
- silica – colloidal anhydrous
- magnesium stearate

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

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

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

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

Flutamin is distributed in New Zealand by: