

Flutamin

contains the active ingredient flutamide

CONSUMER MEDICINE INFORMATION

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 benefits and risks. Your doctor has weighed the risks of you taking Flutamin against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Flutamin is used for

Flutamin is used together with another medicine (LHRH agonists) to treat cancer of the prostate gland. It is also used to prevent "flare" associated with LHRH agonists use.

Flutamin contains the active ingredient flutamide, which is a non-steroidal antiandrogen. This medicine works by blocking the effects of androgens, male hormones, which prostate cancer cells need to grow.

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

Your doctor may have prescribed Flutamin for another reason.

Flutamin is available only with a doctor's prescription.

There is no evidence that Flutamin is addictive.

As prostate cancer only occurs in men, this medicine therefore should not be used in women.

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 which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Flutamin if you have serious liver problems.

Do not take Flutamin if the expiry date (EXP) printed on the pack has passed.

Do not take Flutamin if 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 any medical conditions, especially the following:

* liver problems.

Your doctor may want to take special care if you have this condition.

Tell your doctor if you are pregnant or breastfeeding.

Flutamin is only for use in men.

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

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

* warfarin, a medicine used to prevent blood clots.

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

If you are not sure whether you are taking the above medicine, check with your doctor or pharmacist.

Your doctor and pharmacist have 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.

When to take Flutamin

Take Flutamin every eight hours.

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

How to take Flutamin

Swallow the tablets with a glass of water.

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, even if you start to feel better.

Keep taking Flutamin for as long as your doctor recommends.

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

If you take too much Flutamin (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the 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.

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.

Dizziness and tiredness have been reported 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.

The side effects listed in this section have been reported in people receiving treatment with this medicine either alone and/or in combination with a LHRH agonist.

Do not be alarmed by this list of possible 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:

- * hot flushes (sudden sweating, feelings of warmth)
- * nausea (feeling sick), vomiting
- * diarrhoea
- * dizziness, tiredness, headache
- * difficulty sleeping
- * breast tenderness
- * increased breast size
- * sexual problems.

The above list includes some of the more mild and/or common side effects of your medicine.

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

- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * 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
- * 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
 - tenderness in the right upper stomach
 - flu-like symptoms.
- * increased sensitivity of the skin to the sun.

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.

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

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

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

Other side effects not listed above may also occur in some people.

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 will not keep well.

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

Product description

What it looks like

Flutamin is a round, yellow, scored tablet marked "FT" over "250" on one side and "G" on the other side.

Flutamin is available in packs of 100 tablets.

Ingredients

The active ingredient in Flutamin is flutamide.

Each Flutamin tablet contains 250 mg of flutamide.

The tablets also contain the following inactive ingredients:

- * lactose
- * microcrystalline cellulose
- * maize starch
- * pregelatinised maize starch
- * sodium lauryl sulfate
- * colloidal anhydrous silica
- * magnesium stearate.

Flutamin tablets are gluten free.

Supplier

Flutamin is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

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Medical Information

Phone: 1800 028 365

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Australian registration number:

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