

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flutamide 250 mg Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Flutamide is and what it is used for
2. What you need to know before you take Flutamide
3. How to take Flutamide
4. Possible side effects
5. How to store Flutamide
6. Contents of the pack and other information

1. WHAT FLUTAMIDE IS AND WHAT IT IS USED FOR

Flutamide belongs to a group of medicines called anti-androgens. It blocks the effect of testosterone (male sex hormone) in the body. Flutamide is used to treat prostate cancer. It may be taken with another medicine (called a LHRH agonist) that decreases the levels of testosterone. Flutamide can also be used after surgical castration.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUTAMIDE

Do not take Flutamide:

- if you are allergic to flutamide or any of the other ingredients of this medicine (listed in section 6).

Flutamide treats a condition found only in men. It must not be given to women or children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flutamide if you:

- have liver problems. Your doctor will check your liver function before and during treatment.
- have kidney problems.
- have heart disease.
- are at risk of osteoporosis such as if you are a long term smoker or drinker, have a family history of osteoporosis or are taking medicines to stop epileptic fits (antiepileptics) or medicines to relieve inflammation (corticosteroids) or have osteoporosis (brittle bones) as Flutamide can increase the risk of bone fractures. Your doctor will measure your bone mineral density (BMD) to check you are not at risk; at the beginning of your treatment and then at least on a yearly basis.
- suffer from chest problems such as breathlessness.
- are diabetic.
- have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions. The risk of heart rhythm problems may be increased when using Flutamide.

If you are taking Flutamide long-term you may also have your sperm count checked if it is appropriate.

While taking this medicine you should use an effective barrier method of contraception i.e. condom when engaging in sexual activity.

Other medicines and Flutamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially any of the following:

- medicines that thin the blood such as warfarin
- theophylline, for breathing problems
- medicines that may cause damage to the liver
- medicines that affect the electrical activity of your heart
- leuprorelin, a medicine used to treat some cancers

Flutamide might interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone (used for pain relief and part of drug addiction detoxification), moxifloxacin (an antibiotic), antipsychotics used for serious mental illnesses).

Flutamide with alcohol

You **should not** drink large quantities of alcohol while being treated with this medicine.

Pregnancy and breast-feeding

Flutamide must not be prescribed to women and therefore must not be given to pregnant or breast-feeding mothers.

Driving and using machines

Flutamide may cause tiredness, dizziness or confusion. **Do not** drive or operate machinery if it happens to you.

Flutamide tablets contain lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE FLUTAMIDE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Take the tablets with a glass of water preferably after food every 8 hours.
- Do not chew the tablets. If you do, there is a danger you could overdose because this medicine will be absorbed into your body too quickly.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole. It is not for dividing tablets into equal doses.

Adults (including older people)

The recommended dose is one tablet three times daily, every 8 hours.

You may also be given another medicine with your Flutamide called a LHRH agonist. LHRH agonists (e.g. goserelin, buserelin) are given by injection. In that case, it is very important that the two medicines are taken as directed. You will start your Flutamide treatment either at the same time as or at least a day before taking the LHRH agonist.

If you have had your testicles removed (castrated) you will not be given a LHRH agonist.

Use in children

Flutamide **must not** be given to children.

Patients with liver problems

If you have liver problems your doctor will arrange for you to have regular blood tests.

If you take more Flutamide than you should

You may suffer from methaemoglobinaemia (where your blood cannot deliver as much oxygen to your body as normal). Symptoms can include cyanosis (bluish colouring of the skin), blood that is darker than usual, headache, weakness, confusion, chest pain or vomiting.

If you take more medicine than you should, tell your doctor **immediately** or go to your nearest hospital emergency department.

If you forget to take Flutamide

Take it as soon as you remember unless it is almost time for your next tablet. If this happens, skip the missed tablet and take the next tablet on time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Flutamide

Do not stop taking this medicine, even if you are feeling well, unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects if you take flutamide by itself:

Tell your doctor straight away or go to your nearest hospital emergency department right away if you have any of the following side effects:

Common (may affect up to 1 in 10 people)

- liver disease (hepatitis) which may cause nausea, vomiting, itching, dark coloured urine, pale stools, loss of appetite, yellowing of the skin or whites of the eyes or abdominal pain

Rare (may affect up to 1 in 1,000 people)

- reactions similar to lupus, which can cause joint or muscle pain or swelling, fatigue, general feeling of being unwell, hair loss or a butterfly shaped rash normally across the nose and cheeks
- difficulty breathing, shortness of breath, wheezing or coughing
- diarrhoea containing blood or mucus which may be signs of inflammation of the colon (colitis)

Very rare (may affect up to 1 in 10,000 people)

- lumps in your breast tissue

Not known (cannot be estimated from the available data)

- allergic reactions such as swelling of the lips, tongue, face or throat causing difficulty breathing or swallowing, a rash or swollen itchy skin.
- changes in the electrical activity of the heart (which may show up in tests which show how the heart is working known as "ECG" tests).

Other side effects include:

Very common (may affect more than 1 in 10 people)

- enlarged, painful or tender breast tissue
- production of milk from the breasts

Common (may affect up to 1 in 10 people)

- increased appetite
- difficulty sleeping
- sleepiness
- tiredness
- diarrhoea
- feeling sick (nausea)
- being sick (vomiting)
- blood tests show abnormal liver function

Rare (may affect up to 1 in 1,000 people)

- painful, itchy fluid filled lumpy skin rash commonly known as chicken pox or shingles. This is a sign of nerve or skin infection caused by the herpes virus
- swelling, especially in the arms, legs, chest or genitals (also known as fluid retention)
- bruising
- loss of appetite (anorexia)
- anxiety
- depression
- dizziness
- blurred vision
- other problems with the heart or circulation
- high blood pressure
- constipation
- thirst
- indigestion or stomach pain
- upset stomach
- heartburn
- hives
- changes in hair growth pattern
- hair loss
- muscle cramps
- reversible increases in blood testosterone levels as seen in a blood test
- reduced sperm counts as seen in a fertility test
- decreased sex drive
- unusual weakness (asthenia)
- headache
- chest pain
- general feeling of being unwell
- hot flushes

Very rare (may affect up to 1 in 10,000 people)

- cough
- rash or blisters resulting from skin sensitive to strong or long periods of sunlight

Possible side effects if you take flutamide with LHRH agonists

The following side effects have been seen in patients taking Flutamide together with LHRH agonist treatment. They could be additional side effects or the same as above but seen more commonly:

Tell your doctor straight away or go to your nearest hospital emergency department right away if you have any of the following side effects:

Rare (may affect up to 1 in 1,000 people)

- lack of white blood cells which may cause more frequent infections such as fever, sore throat or mouth ulcers

Very rare (may affect up to 1 in 10,000 people)

- serious skin reactions such as painful red areas, fluid filled blisters or peeling of layers of skin
- pale, yellow or bluish colouring of the skin especially around the lips, blood that is darker than normal, loss of appetite, headache, vomiting, weakness, chest pain, cold or numb hands or feet which are signs that your blood cannot deliver as much oxygen to the body as normal
- mood or personality changes, disorientation, forgetfulness, mental foginess. These are signs of a disease of the brain caused by liver problems

Not known (cannot be estimated from the available data)

- severe pain or swelling in one of your legs, sudden severe chest pain that might spread to your left arm, sudden breathlessness, sudden cough without an obvious cause, problems speaking, irregular muscle movements, sudden severe stomach pain, weakness, strange feeling or numbness in any part of the body. This may suggest you have a blood clot.

Other side effects include:

Very common (may affect more than 1 in 10 people)

- hot flushes
- decreased sex drive
- problems getting or maintaining an erection
- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea

Rare (may affect up to 1 in 1,000 people)

- bleeding or bruising more easily or for a longer time. These may be signs of a lack of platelets (blood clotting cells) in the blood
- numbness or lack of sense of touch
- confusion
- nervousness
- nerve or muscle problems
- joint or muscle pain
- reduced bone mineral density or osteoporotic disorders (these can mean you are more likely to suffer broken bones)
- painful urination
- changes in how often you urinate
- change in urine colour to amber or yellow-green
- skin irritation where the LHRH agonist was injected
- raised levels of blood urea and creatinine seen in a blood test

Very rare (may affect up to 1 in 10,000 people)

- raised blood sugar levels
- worsening of existing diabetes

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE YOUR MEDICINE

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the packaging after “EXP”. The expiry date refers to the last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Flutamide contains

The active substance is flutamide. Each tablet contains 250 mg flutamide.

The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2 ‘Flutamide contains lactose’), pregelatinised maize starch, sodium laurilsulfate, colloidal anhydrous silica, magnesium stearate.

What Flutamide tablets look like and contents of the pack

The tablets are yellow, curved on both sides and marked ‘FT’ score ‘250’ on one side and ‘G’ on the other.

Flutamide tablets are available in blister packs or plastic pots containing 20, 21, 30, 50, 60, 84, 100, 105, 250 or 10 x 21 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer:

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