

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 Tablets are and what they are used for
2. What you need to know before you take Flutamide Tablets
3. How to take Flutamide Tablets
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1. What Flutamide Tablets are and what they are used for

The name of your medicine is Flutamide 250 mg Tablets (referred to as Flutamide Tablets in this leaflet).

Flutamide Tablets contain the active ingredient flutamide, which belongs to a group of medicines called non-steroidal antiandrogens, which stop the effects of male sex hormones.

Flutamide Tablets are used to treat advanced prostate cancer in men. The prostate is a walnut shaped gland found next to the bladder. Prostate cancer leads to uncontrolled growth of the prostate and may also spread to the bones causing pain in the back, hips and pelvis. Prostate cancer is dependent on male sex hormones for growth. By stopping the effects of these hormones it is possible to slow down or shrink the tumour both in the prostate and areas where it has spread to.

Your doctor may prescribe these tablets in combination with other drugs that block male sex hormones called LHRH (luteinising hormone-releasing hormone) agonists, or after orchidectomy (an operation on the testes).

2. What you need to know before you take Flutamide Tablets

Do not take Flutamide Tablets

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

Warnings and precautions

Talk to your doctor before taking Flutamide Tablets

- if you have any liver or kidney problems.
- if you 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 Tablets.
- if you 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.
- if you suffer from chest problems such as breathlessness.
- if you are taking Flutamide Tablets long-term you may also have your sperm count checked if it is appropriate.
- Flutamide is only for use in male patients. Contraceptive measures should be taken during treatment.

If any of these apply to you, or you are not sure, tell your doctor.

Other medicines and Flutamide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including any medicines obtained without a prescription.

This is especially important if you are taking the following medicines:

- warfarin (or any other blood thinning drugs),
- theophylline (for breathing problems).

Flutamide Tablets 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 Tablets with alcohol

Excessive consumption of alcohol should be avoided while taking Flutamide Tablets.

Pregnancy and breast-feeding

Flutamide Tablets should only be used by male patients. The safety of flutamide in pregnant or breast-feeding women has not been studied.

Laboratory tests

Your doctor will want to check your blood regularly. Based on these tests, your doctor may decide that you stop taking Flutamide Tablets or reduce the dose. If you have any signs of liver injury such as jaundice (looking yellow), dark urine, itching, persistent loss of appetite, abdominal pain or flu-like symptoms, you should stop taking Flutamide Tablets and contact your doctor immediately.

If you have not undergone castration, either surgical or with medicines, your doctor may decide to have regular sperm counts performed.

Driving and using machines

Possible side effects such as tiredness, dizziness and confusion have been reported with flutamide use which may impair the ability to drive and use machines. Do not drive or operate machinery if you are affected in this way.

Flutamide Tablets contain lactose

Flutamide Tablets contain lactose monohydrate, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Flutamide Tablets

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

The recommended dose

The usual dose is one tablet three times daily.

You may have also been prescribed another drug called an LHRH agonist. LHRH agonists (e.g. goserelin, busserelin) are given by injection. In that case, it is very important that the two medicines are taken as directed. You will start your Flutamide Tablets treatment at least three days before having the LHRH agonist.

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

These tablets should be taken as instructed, with a glass of water. Continue to use them for as long as your doctor tells you, it may be dangerous to stop without his/her advice.

Flutamide Tablets and the elderly

If you are elderly it is particularly important to take this medicine exactly as directed by your doctor.

Use in children

Flutamide Tablets must not be given to children.

If you take more Flutamide Tablets than you should

If you realize you have taken more Flutamide Tablets than your doctor has recommended (or if someone else has taken some of your Flutamide Tablets), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

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 forget to take Flutamide Tablets

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Flutamide Tablets

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

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.

Serious side effects

If you notice any of the following, **stop taking** Flutamide Tablets and contact your doctor immediately:

- an allergic reaction to any of the ingredients of Flutamide

- Tablets (such as itching and/or rash, swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing)
- problems with your liver (such as itching of the skin, dark urine, lack of appetite, yellow eyes or skin, flu-like symptoms, irritability, changes in the level of consciousness)
- swelling of legs or any other parts of the body

Other side effects

Other side effects of Flutamide Tablets include:

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

- enlarged and/or tender breasts, breast milk production
- These effects will get better if your dose is reduced or you are told to stop taking your medicine.

Common (affects less than 1 in 10 people)

- brief abnormal liver function
- diarrhoea
- feeling sick (nausea)
- being sick (vomiting)
- increased appetite
- feeling tired
- sleepiness
- difficulty sleeping

Rare (affects less than 1 in 1000 people)

- swelling
- chest pain
- dizziness
- headache
- abdominal problems such as indigestion or upset stomach
- inflammation of the colon
- heartburn
- constipation (infrequent or difficult bowel movement)
- itchiness
- bruises
- swollen ankles
- poor appetite
- nerve and skin infection caused by the herpes virus
- hot flushes
- weakness
- thirst
- lupus-like syndrome (lupus erythematosus is a disease affecting the skin and can cause inflammation, a rash on the face, red scaly patches on the skin)
- disturbances of vision
- decreased sex drive, decreased sperm production
- anxiety
- depression
- breathing difficulties
- problems with the heart or circulation
- high blood pressure
- hives
- changes in hair growth pattern, hair loss
- muscle cramps
- reversible increases in blood testosterone levels
- malaise

Very rare (affects less than 1 in 10000 people)

- sensitivity to sunlight
- male breast cancer
- cough
- sudden kidney failure

Unknown (frequency cannot be estimated from the available data)

- changes in ECG (QT prolongation)

When Flutamide Tablets are taken at the same time as an LHRH agonist

The following side effects have been seen in patients taking Flutamide Tablets together with LHRH agonist treatment. They could be additional or the same as above but with a different frequency.

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

- diarrhoea
- feeling sick (nausea)
- being sick (vomiting)
- hot flushes
- decreased sex drive
- being unable to get an erection (impotence)

Rare (affects less than 1 in 1000 people)

- reduced red blood cell count which can make the skin pale and cause weakness or breathlessness
- reduced white blood cell count which may cause more frequent infections
- reduced number of blood platelets which increases the risk of bleeding or bruising
- muscle or nerve problems
- enlarged breasts
- drowsiness
- confusion
- nervousness
- gastrointestinal disorders
- abdominal pain
- rash
- joint and muscle pain
- reduced bone mineral density or osteoporotic disorders (these

can mean you are more likely to suffer broken bones)

- painful urination
- changes in frequency of urination
- changes in urine colour to amber or yellow-green

Very rare (affects less than 1 in 10000 people)

- red blood disorders such as abnormal blood pigment levels
- difficulty breathing
- high blood pressure
- lung disease
- cholestatic jaundice (when the flow of bile from the liver is blocked)
- disease of the brain caused by liver illness
- redness of the skin
- skin ulcers
- increased blood sugar, worsening of diabetes
- eruption of blisters
- raised levels of blood urea and creatinine

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Flutamide Tablets

Keep this medicine out of the sight and reach of children. Flutamide Tablets should not be stored above 25°C. Store in a dry place in the original package.

Do not use the tablets if the strip in which they are packaged is damaged.

Do not use this medicine after the expiry date that is stated on the blister strip and the outer carton after EXP. The expiry date refers to the last day of that 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 Tablets contain

Each Flutamide Tablet contains 250 mg of the active ingredient flutamide.

The other ingredients are: lactose monohydrate, sodium lauryl sulphate, microcrystalline cellulose, maize starch, colloidal anhydrous silica and magnesium stearate.

What Flutamide Tablets look like and the contents of the pack

Flutamide Tablets are uncoated, have a yellow colour and are marked FT 250.

Flutamide Tablets are available in blister calendar packs containing 84 tablets.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation Holder

Sovereign Medical, Sovereign House,
Miles Gray Road, Basildon, Essex, SS14 3FR.

Manufacturer

Waymade Plc,
Josselin Road,
Burnt Mills Industrial Estate,
Basildon, Essex, SS13 1QF.

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