

Package leaflet: Information for the user

Flutamid Stada 250 mg tablets Flutamide

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

1. What Flutamid STADA is and what it is used for

Flutamid STADA contains the active substance Flutamide. This belongs to a group of medicines that interfere with some of the actions of male sex hormones in the body.

Flutamid STADA may be used to treat cancer of the prostate gland. The prostate is a gland at the base of the bladder, found only in men. Flutamide STADA can be used alone or in combination with other medicines that block male sex hormones called LHRH (luteinising hormone releasing hormone) agonists. It can also be used in men who have had their testicles surgically removed.

2. What you need to know before you take Flutamid STADA

THIS PRODUCT IS NOT FOR USE BY WOMEN

Do not take Flutamid STADA if:

- you are allergic to flutamide or any of the other ingredients of this medicine (listed in section 6);
- you currently have serious problems with your liver.

Tell your doctor if you are not sure about any of the above.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flutamid STADA

- If you have any problems with your liver or kidneys.
- 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 Flutamid STADA.
- If you start to suffer from any signs of hepatitis such as:
 - jaundice (yellowing of the skin and whites of the eyes),
 - itching,
 - dark-coloured urine,

- abdominal pain,
- tiredness,
- loss of appetite,
- feeling sick or being sick

During your course of treatment your doctor may need to check the effects with regular blood tests.

- If you have problems with your heart and you have not had any surgery or medicines to inactivate your testicles. (In patients with heart disease and normal working testicles, flutamide may cause the heart to work harder through a build-up of fluid in the circulation).

Other medicines and Flutamid STADA

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Flutamid STADA 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).

Always inform your doctor or pharmacist if you are taking the following medicine as its effect may be changed; your doctor may need to change the dose:

- medicines which prevent blood clots, called anticoagulants.

Taking Flutamid STADA with food, drink and alcohol

The tablets should be swallowed whole with a glass of water after meals. You should avoid taking excessive alcohol whilst you are being treated with Flutamid STADA.

Pregnancy and breast-feeding

This medicine is not for use in women. Patients should use appropriate contraceptive measures (condoms) during treatment.

Driving and using machines

After starting treatment with Flutamid STADA you may feel tired. This effect should wear off as your treatment continues. If you do feel drowsy do not drive or operate any tools or machines until the effect wears off.

Flutamid STADA contains 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 Flutamid STADA

Always take this medicine exactly as your doctor has told you. Your doctor will tell you how many tablets to take, and when to take them. Check with your doctor or pharmacist if you are not sure. It is important to take the right dose at the right time.

The normal recommended dosage is one tablet (250 mg) three times daily taken at eight hour intervals. However, the dose will be decided by your doctor to suit your particular needs.

Flutamid STADA tablets should be taken with a glass of water preferably after meals.

You should continue taking the tablets until the course prescribed by your doctor is finished. It is important not to stop taking the tablets just because you are starting to feel better. When you have nearly completed the prescribed course, check with your doctor whether your medication needs to be continued or if you can stop taking this medicine.

If you take more Flutamid STADA than you should

If you accidentally take too many tablets, call your doctor straight away, or go to the nearest hospital casualty department. Always take any left-over tablets with you, as well as the container and this leaflet, so that the medical staff knows what you have taken.

If you forget to take Flutamid STADA

If you miss a whole day's dose, take the normal dose on the next day. Do not take a double dose to make up for a forgotten dose. If you are not sure ask your doctor or pharmacist for advice.

If you stop taking Flutamid STADA

DO NOT stop or change your treatment before talking to your doctor.

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.

IMPORTANT: If you experience itching, *jaundice* (yellowing of the skin and whites of the eyes), dark urine, loss of appetite, tummy pain or flu-like symptoms stop taking your medicine and contact your doctor **as soon as possible**.

When Flutamid STADA tablets are taken alone:***Very common (may affect more than 1 in 10 people):***

- The most common side effect is tenderness and enlargement of the area around the nipples. The nipples may also produce a milky-white fluid. However, these effects are only temporary and will disappear when you stop taking Flutamid STADA or your doctor recommends the dose is reduced. These effects are less likely to occur when Flutamid STADA is taken at the same time as an LHRH agonist.

Common (may affect up to 1 in 10 people):

- Other side effects which occur less frequently are nausea; vomiting; diarrhoea; increased appetite; difficulty sleeping; tiredness and liver problems.

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

- Rarely, a few people may suffer from decreased sex drive; upset stomach; loss of appetite; ulcer-like pain; heartburn; constipation; swelling of feet and lower legs; bruising of skin; shingles; itching; an inflammatory disease affecting the skin and joints (lupus-like syndrome); feeling flushed; headache; dizziness; a feeling of general discomfort; blurred vision; thirst; chest pain; anxiety; depression; swelling of the lymph nodes.
- If you take Flutamid STADA for a long time, your sperm count may go down.

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

- Very rarely cancer of the breast in men and sun allergy (photosensitivity) have been reported.

Not known (frequency cannot be estimated from the available data):

- changes in ECG (QT prolongation)

When Flutamid STADA tablets are taken at the same time as an LHRH agonist:***Very common (may affect more than 1 in 10 people):***

- The most common side effects are hot flushes; decreased sex drive or sexual ability; diarrhoea; nausea and vomiting.

Uncommon (may affect up to 1 in 100 people):

- Breast enlargement in men.
- Inflammation of the liver (hepatitis)

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

- Rare side effects include blood disorders; liver problems, jaundice (yellowing of the skin and whites of the eyes); loss of appetite; upset stomach; rash; swelling of feet or lower legs; muscle ache or twitching; high blood pressure; drowsiness; depression; confusion; anxiety and nervousness; urogenital problems.

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

- Contact your doctor immediately if you have severe respiratory problems. This has been reported very rarely.
- Very rarely, certain types of anaemia (lack of blood) have been reported
- Very occasionally a few people have also suffered from sensitivity to light and change in urine colour to amber or yellow-green.
- You should see your doctor immediately if you develop itching, blistering and reddening of the skin.
- Very rarely, the amount of sugar in your blood may increase. If you already have diabetes mellitus, the dose of the medicine used to control it may need adjustment by your doctor.
- You should see your doctor immediately if you develop itching of the skin; dark urine; persistent lack of appetite; yellow eyes or skin; tenderness in the right upper abdomen or “flu-like” symptoms. These symptoms may indicate a liver disorder, which has been reported very rarely in a few people taking flutamide.

Not known (frequency cannot be estimated from the available data):

- In addition formation of blood clots which may cause a blockage of a blood vessel may occur.

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 national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Flutamid STADA

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister pack and the outer carton after Exp. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Flutamid STADA contains

The active substance is Flutamide. 1 tablet Flutamid STADA contains 250 mg Flutamide.

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

What Flutamid STADA looks like and contents of the pack

There is only one strength of Flutamid STADA tablets. They are pale yellow round tablets. They are available in packs of 21, 50, 84, 90, 100, 105 or 200 tablets.

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer

[to be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Flutamide EG 250 mg
Italy:	Flutamide EG 250 mg compresse
Luxembourg:	Flutamide EG 250 mg
Sweden:	Flutamid Stada

This leaflet was last revised in Mars 2020.