

Package leaflet: Information for the user

Fareston 60 mg tablets toremifene

Read all of this leaflet carefully before you start using 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 Fareston is and what it is used for
2. What you need to know before you take Fareston
3. How to take Fareston
4. Possible side effects
5. How to store Fareston
6. Contents of the pack and other information

1. What Fareston is and what it is used for

Fareston contains the active substance toremifene, an anti-estrogen. Fareston is used for the treatment of a certain type of breast tumour in women who have had their menopause.

2. What you need to know before you take Fareston

Do not take Fareston

- if you are allergic to toremifene or any of the other ingredients of this medicine (listed in section 6)
- if you have a thickening of the womb lining
- if you have severe liver problems
- if you were born with or have had any condition which causes certain abnormal changes in the electrical recording of the heart (electrocardiogram or ECG)
- if you have a salt imbalance in the blood, especially low concentrations of potassium in the blood (hypokalaemia) which are currently not corrected by treatment
- if you have a very slow heart rate (bradycardia)
- if you have a heart failure
- if you have a history of abnormal heart rhythms (arrhythmias)
- if you are taking other medicines that may affect your heart (see section 2 Other medicines and Fareston).

This is because Fareston can affect your heart by delaying the conduction of electrical signals within your heart (prolongation of QT-interval).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fareston:

- if you have unstable diabetes
- if your general well-being is severely deteriorated
- if you have previously had a condition in which blood clots formed in blood vessels, for example in your lungs (lung embolism) or in the veins of your legs (deep vein thrombosis)

- if you experience an abnormal heart rhythm whilst taking Fareston. Your doctor may advise you to stop taking Fareston and perform a medical test to see how your heart is working (ECG) (see section 2 Do not take Fareston).
- if you have any heart condition, including chest pain (angina)
- if your cancer has spread to the bones (bone metastasis) as calcium blood levels may increase at the beginning of treatment with Fareston. Your doctor will conduct regular medical check-ups.
- if you have been told by your doctor that you have an intolerance to certain sugars, like lactose (see section 2 Fareston contains lactose).

You should have gynaecological examinations before you start treatment with Fareston and at least once a year following the start of treatment with Fareston. Your doctor will conduct regular medical check-ups if you have high blood pressure, diabetes, have taken hormone replacement therapy or if you are obese (BMI over 30).

Other medicines and Fareston

Tell your doctor if you are taking, have recently taken or might take any other medicines. The dose of some of these may have to be adjusted while you are on Fareston. In particular please tell your doctor if you are taking any of the following:

- water tablets (diuretics of thiazide type)
- medicines to prevent blood clotting such as warfarin
- medicines used to treat epilepsy such as carbamazepine, phenytoin, phenobarbital
- medicines used to treat fungal infections such as ketoconazole, itraconazole, voriconazole, posaconazole
- medicines used to treat bacterial infections (antibiotics) such as erythromycin, clarithromycin and telithromycin
- medicines used to treat viral infection such as ritonavir and nelfinavir.

Do not take Fareston together with the following medicines as there is an increased risk that your heartbeat may be altered (see section 2 Do not take Fareston):

- medicines used to treat abnormal heart rhythm (antiarrhythmics); such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide and ibutilide
- medicines used to treat mental and behavioral disorders (neuroleptics); such as phenothiazines, pimozide, sertindole, haloperidol and sultopride
- medicines used to treat infections (antimicrobials); such as moxifloxacin, erythromycin (infusion) pentamidine and antimalarials (particularly halofantrine)
- certain medicines to treat allergies; such as terfenadine, astemizole and mizolastine
- others; cisapride, intravenous vincamine, bepridil, diphemanil.

If you are admitted to the hospital or if you are prescribed a new medicine, please tell your doctor that you are taking Fareston.

Pregnancy and breast-feeding

Do not use Fareston during pregnancy or breast feeding.

Driving and using machines

Fareston has no influence on the ability to drive and use machines.

Fareston contains lactose

Fareston contains 28.5 mg lactose (as monohydrate) per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Other excipients

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

3. How to take Fareston

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The usual dose is one 60 mg tablet taken orally, once daily. Fareston can be taken with or without food.

If you take more Fareston than you should

Contact your doctor, pharmacist or the nearest hospital immediately. Symptoms of overdose may be dizziness and headache.

If you forget to take Fareston

If you miss one dose take the next tablet as usual and continue treatment as recommended. Do not take a double dose to make up for a forgotten tablet. If you have missed several doses, please inform your doctor and follow his instructions.

If you stop taking Fareston

The treatment with Fareston should only be stopped when advised by 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.

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

- hot flushes, sweating.

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

- fatigue, dizziness, depression
- nausea (feeling sick), vomiting
- rash, itching, oedema (swelling)
- uterine bleeding, white discharge.

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

- headache, sleep disorders
- weight increase, constipation, loss of appetite
- thickening of the lining of the womb (endometrial hypertrophy)
- blood clot for example in the lung (thromboembolic events)
- shortness of breath.

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

- a feeling of spinning (vertigo)
- growth on the lining of the womb (endometrial polyps)
- increase in liver enzymes (increase of liver transaminases).

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

- changes in the lining of the uterus (endometrium), cancer of the lining of the womb (endometrial cancer)
- hair loss (alopecia)
- cloudiness of the eye surface (transient corneal opacity)
- yellowing of the skin or whites of the eyes (jaundice).

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

- low number of white blood cells, which are important in fighting infection (leukopenia)
- low number of red blood cells (anaemia)
- low number of platelets (thrombocytopenia)

- inflammation of the liver (hepatitis)
- high blood levels of triglycerides, a type of fat.

You should contact your doctor immediately if you notice any of the following:

- swelling or tenderness in your calf
- unexplained shortness of breath or sudden chest pain
- vaginal bleeding or changes in vaginal discharge.

Fareston causes certain abnormal changes in the electrical recording of the heart (electrocardiogram or ECG). See section 2 Warnings and precautions.

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 Website: 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 Fareston

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

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

This medicine does not require any special storage conditions.

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 Fareston contains

- The active substance is toremifene; each tablet contains 60 mg (as citrate).
- The other ingredients are maize starch, lactose monohydrate, povidone, sodium starch glycolate, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

What Fareston looks like and contents of the pack

White, round, flat, bevelled edge tablet with TO 60 on one side.
30 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

Orion Corporation Orion Pharma
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FI-24100 Salo
Finland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Orion Pharma (UK) Ltd, Abbey Gardens, 4 Abbey Street, Reading, RG1 3BA

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