

FARESTON®

Toremifene

Consumer Medicine Information

What is in this leaflet

The name of your medicine is FARESTON. It contains an active ingredient called toremifene.

This leaflet answers some common questions about FARESTON.

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 risks and benefits. Your doctor has weighed the risks of you taking FARESTON against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What FARESTON is used for

FARESTON is used to treat hormone-sensitive breast cancer in women who have had their menopause.

It belongs to the group of medicines known as anti-oestrogens. It helps to stop the tumour cells from growing and multiplying.

A doctor's prescription is required for FARESTON.

Your doctor, however, may prescribe FARESTON for another purpose.

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

Before you take FARESTON

When you must not take it

Do not take FARESTON if:

- you have endometrial hyperplasia (an overgrowth in the lining of the uterus)
- you have severe liver failure
- you are pregnant or breastfeeding
- you have a heart condition called QT prolongation, where the heart muscle takes longer to contract and then recover due to a disorder involving electrical impulses.
- you have other heart conditions including bradycardia (slow heart rhythm), symptomatic arrhythmias (irregular heart rhythm) or heart failure.
- you have electrolyte disturbances including uncorrected hypokalaemia (low blood potassium levels; which can in turn cause heart arrhythmia disorders).

FARESTON is for use by women who have had their menopause and should not be used by pregnant or breastfeeding women.

Do not take FARESTON after the expiry date (EXP) printed on the pack.

Do not take FARESTON if the packaging is torn or shows sign of tampering.

If you are not sure if you should start taking FARESTON, contact your doctor or pharmacist.

Before you start to take it

You must tell your doctor if:

1. you are allergic to:

- toremifene or other anti-oestrogens (e.g. tamoxifen) or any of the ingredients listed at the end of this leaflet.

• any other medicines

• any other substances such as foods, preservatives or dyes

2. you have angina or a heart condition, including an irregular heart beat

3. you feel pain in your bones

4. you have had problems with blood clots in the past

In severe cases, FARESTON is not recommended.

5. you have liver problems

6. you have any other medical conditions or health problems

If you have not told your doctor about any of the above, report them before you take any FARESTON.

Taking other medicines

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

Some medicines and FARESTON may interfere with each other. These include:

- some diuretics, also called water or fluid tablets
- phenytoin, carbamazepine and phenobarbitone, medicines used to treat epilepsy
- warfarin, a medicine used to stop blood clots, and related medicines
- certain antibiotics such as erythromycin and related

- medicines (including, moxifloxacin and pentamidine).
- Certain antimalarials, particularly halofantrine.
- certain medicines used to treat fungal infections, such as ketoconazole
- Certain antiarrhythmics, including class IA (eg quinidine, hydroquinidine, disopyramide) and class III (eg amiodarone, sotalol, doretilide, ibutilide)
- Some antihistamines, such as terfenadine, astemizole and mizolastine.

These medicines may be affected by FARESTON, or may affect how well FARESTON works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information about medicines to be careful with or avoid while taking FARESTON.

How to take FARESTON

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 box, ask your doctor or pharmacist for help.

How much to take

The usual dose is one tablet by mouth, once a day.

However, your doctor may prescribe a different dose.

How to take it

Swallow FARESTON tablets with a glass of water.

When to take it

FARESTON can be taken with or without food. It is good practice to take FARESTON at about the same time each day.

How long to take it

Continue to take FARESTON regularly, even when you begin to feel better.

Do not stop taking this medicine without first checking with your doctor.

Your doctor will tell you when to stop taking FARESTON.

If you forget to take it

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 it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (Ph 13 11 26 - Australia) for advice, or go to the emergency department at your nearest hospital, if you think you or anyone else may have taken too much FARESTON. Do this even if there are no signs of discomfort or poisoning.

Keep this telephone number handy.

Very high doses of FARESTON may make you feel dizzy or give you a headache.

While you are taking FARESTON

Things you must do:

Use FARESTON exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking FARESTON.

If you are about to be started on any new medicines tell your doctor or pharmacist that you are taking FARESTON.

If you become pregnant while taking FARESTON tell your doctor immediately.

Things you must not do

Do not take FARESTON to treat any other complaints unless your doctor tells you to.

Do not give FARESTON to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Make sure you know how you react to FARESTON before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

As with other medicines, FARESTON may cause dizziness or light-headedness in some people.

If this occurs, do not drive.

Side effects

Check with your doctor as soon as possible if you have any problems while you are taking FARESTON, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines FARESTON can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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.

These are the more common side effects of FARESTON:

- hot flushes
- sweating
- nausea (feeling sick) or vomiting
- a white vaginal discharge
- dizziness
- swelling of the hands, feet and/or ankles (oedema)
- pain

Other side effects that may occur include:

- vaginal bleeding
- chest pain, back pain
- muscle weakness
- headache, light-headedness
- inability to sleep (insomnia)
- weight increase
- shortness of breath
- tremor, weakness, tiredness
- itching
- skin discolouration or yellowing of the eyes and/or skin (jaundice)
- constipation
- loss of appetite (anorexia)
- reduced vision

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

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using FARESTON

Storage

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 the tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store FARESTON in the freezer.

Do not store FARESTON or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

Return any unused medicine to your pharmacist.

Product description

What it looks like

FARESTON tablets are white or almost white, flat, round, uncoated tablets marked with TO60 on one side of the tablet. It is available in blister packs of 30 tablets.

Ingredients

Active ingredient

Toremifene citrate equivalent to toremifene 60 mg/tablet.

Inactive ingredients

- microcrystalline cellulose
- lactose
- maize starch
- sodium starch glycollate
- povidone

- magnesium stearate
- colloidal anhydrous silica

Sponsor

Fareston is supplied in Australia by:

Orion Pharma (Aus) Pty Limited
Level 24, Tower 3
300 Barangaroo Avenue, Sydney,
NSW 2000, Australia
Telephone: 1800 861 913

Australian Registration Number

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