

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using FARESTON?

FARESTON contains the active ingredient toremifene citrate. FARESTON is used to treat hormone-sensitive breast cancer in women who have had their menopause

For more information, see Section [1. Why am I using FARESTON?](#) in the full CMI.

### 2. What should I know before I use FARESTON?

Do not use if you have ever had an allergic reaction to toremifene citrate, other anti-oestrogens (e.g. tamoxifen), or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use FARESTON?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with FARESTON and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use FARESTON?

- The usual dose is one tablet once a day.
- More instructions can be found in Section [4. How do I use FARESTON?](#) in the full CMI.

### 5. What should I know while using FARESTON?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using FARESTON.</li><li>• Keep all of your doctor's appointments so that your progress can be checked. You will need to have regular gynaecological check-ups while you are taking FARESTON.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how FARESTON affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store FARESTON below 25 °C.</li></ul>

For more information, see Section [5. What should I know while using FARESTON?](#) in the full CMI.

### 6. Are there any side effects?

Less serious side effects include: sweating, itching, rash, nausea or vomiting, dizziness, depression, mood changes or shortness of breath, swelling of the hands, feet and/or ankles, pain, tiredness or hot flushes. Serious side effects include: a white vaginal discharge, heavy menstrual periods, blood clot in blood vessel, liver problems or high levels of calcium in your blood.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# FARESTON®

Active ingredient(s): *toremifene citrate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using FARESTON. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FARESTON.**

Where to find information in this leaflet:

- [1. Why am I using FARESTON?](#)
- [2. What should I know before I use FARESTON?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FARESTON?](#)
- [5. What should I know while using FARESTON?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using FARESTON?

FARESTON contains the active ingredient **toremifene citrate**. FARESTON belongs to the group of medicines known as anti-oestrogens. It helps to stop the tumour cells from growing and multiplying.

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

## 2. What should I know before I use FARESTON?

### Warnings

**Do not use FARESTON if:**

- you are allergic to toremifene citrate, other anti-oestrogens (e.g. tamoxifen), or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you have endometrial hyperplasia (an overgrowth in the lining of the uterus)
- you have severe liver failure
- you are pregnant
- 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).

## Check with your doctor if you:

- have any other medical conditions, particularly:
  - angina or a heart condition, including an irregular heart beat
  - feel pain in your bones
  - have had problems with blood clots in the past. In severe cases, FARESTON is not recommended.
  - liver problems
  - have any other medical conditions or health problems
- are lactose intolerant. FARESTON tablets contain lactose.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with FARESTON and affect how it works.**

In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat irregular heartbeat such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, doretilide and ibutilide.
- prochlorperazine, a medicine used to treat nausea and dizziness
- medicines used to treat mental illness such as phenothiazides, pimozide, sertindole, haloperidol, sultopride, chlorpromazine.
- certain antibiotics such as erythromycin and related medicines (including clarithromycin, moxifloxacin and pentamidine, telithromycin, troleandomycin).
- certain antimalarials, particularly halofantrine.
- some antihistamines, such as terfenadine, astemizole and mizolastine
- 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 medicines used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole and posaconazole.
- medicines used to treat HIV infection such as ritonavir and nelfinavir
- cisapride
- bepridil
- diphemanil.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FARESTON.**

## 4. How do I use FARESTON?

### How much to take

- The usual dose is one tablet once a day.
- Follow the instructions provided and use FARESTON until your doctor tells you to stop.

### When to take FARESTON

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

### How to take FARESTON

- Swallow FARESTON tablets with a glass of water.

### How long to take FARESTON

- Take FARESTON for as long as your doctor tells you.

### If you forget to use FARESTON

FARESTON should be used regularly at the same time each day.

**If you miss your dose at the usual time, and 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 you missed.**

### If you use too much FARESTON

If you think that you have used too much FARESTON, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using FARESTON?

### Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

- You will need to have regular gynaecological check-ups while you are taking FARESTON.
- FARESTON can cause problems with your blood and liver. Your doctor may organise blood tests to check for these problems.

Remind any doctor, dentist or pharmacist you visit that you are using FARESTON.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how FARESTON affects you.**

FARESTON may cause dizziness or light-headedness in some people and may affect your ability to drive.

### Drinking alcohol

Tell your doctor if you drink alcohol.

### Looking after your medicine

- Store FARESTON below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Skin related:</b> <ul style="list-style-type: none"> <li>• sweating</li> <li>• itching, rash</li> </ul>	<b>Speak to your doctor if you have any of these less serious side</b>

Less serious side effects	What to do
<p><b>Stomach and gut related:</b></p> <ul style="list-style-type: none"> <li>nausea (feeling sick) or vomiting</li> </ul> <p><b>Nerve related:</b></p> <ul style="list-style-type: none"> <li>dizziness</li> </ul> <p><b>Mental related:</b></p> <ul style="list-style-type: none"> <li>depression</li> <li>mood changes</li> </ul> <p><b>Lung related:</b></p> <ul style="list-style-type: none"> <li>shortness of breath</li> </ul> <p><b>General related:</b></p> <ul style="list-style-type: none"> <li>swelling of the hands, feet and/or ankles (oedema)</li> <li>pain</li> <li>tiredness</li> <li>hot flushes</li> </ul>	<p><b>effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Reproductive system related:</b></p> <ul style="list-style-type: none"> <li>a white vaginal discharge</li> <li>vaginal bleeding</li> <li>heavy menstrual periods</li> </ul> <p><b>Signs of blood clot in blood vessel:</b></p> <ul style="list-style-type: none"> <li>weakness or paralysis on one side of the body or face, difficulty speaking or swallowing, headache, loss of balance or vision (signs of a stroke)</li> <li>pain, swelling, redness and warmth in the leg (signs of a blood clot in the leg)</li> <li>shortness of breath, chest pain and cough (signs of blockage of lung artery)</li> </ul> <p><b>Signs of liver problems:</b></p> <ul style="list-style-type: none"> <li>yellowing of the eyes and/or skin (jaundice)</li> <li>nausea, vomiting, loss of appetite, itchy skin, pale coloured stools, dark coloured urine</li> </ul> <p><b>Signs of high levels of calcium in your blood:</b></p> <ul style="list-style-type: none"> <li>extreme thirst, frequent urination, stomach pain or upset, tiredness, muscle aches or bone pain.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Some of side effects can only be found when your doctor does blood or other tests from time to time to check your progress.

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What FARESTON contains

<b>Active ingredient (main ingredient)</b>	Each tablet contains toremifene citrate equivalent to 60 mg of toremifene
<b>Other ingredients (inactive ingredients)</b>	microcrystalline cellulose lactose monohydrate maize starch sodium starch glycollate povidone magnesium stearate colloidal anhydrous silica
<b>Potential allergens</b>	lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

### What FARESTON 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 (AUST R 59743).

### Who distributes FARESTON

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

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