

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I taking FEMARA?

FEMARA contains the active ingredient letrozole. FEMARA is used to treat breast cancer in post-menopausal women. For more information, see Section [1. Why am I taking FEMARA?](#) in the full CMI.

### 2. What should I know before I take FEMARA?

Do not use if you have ever had an allergic reaction to letrozole 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. Your doctor will want to check your hormone levels to ensure you are no longer having periods. Your doctor may also send you for tests to check on your heart, liver, kidneys, and bones.**

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

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

Some medicines may interfere with FEMARA 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 take FEMARA?

- The usual dose is one (1) FEMARA tablet a day, ideally at the same time each day to help you remember to take it.
- Swallow your tablet whole with a glass of water or other liquid.

More instructions can be found in Section [4. How do I take FEMARA?](#) in the full CMI.

### 5. What should I know while taking FEMARA?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are taking FEMARA.</li><li>• Keep all your doctor's appointments so that your progress can be checked.</li><li>• Promptly get all blood tests, bone tests and any other tests on your liver, heart or kidneys done.</li><li>• Use effective contraception (birth control) to avoid becoming pregnant.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly.</li><li>• Do not give this medicine to someone else.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• FEMARA may make you feel tired or dizzy and may impair your driving.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• FEMARA may make you feel tired or dizzy. Alcohol may increase this effect.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store it in a cool dry place below 30°C (room temperature) away from moisture, heat, or sunlight.</li></ul>

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

### 6. Are there any side effects?

More common side effects include muscle/joints/back/breast pain, raised blood pressure/cholesterol, feeling tired, sick, annoyed, anxious, nervous, dizzy; headache, vertigo, hot flush, vomiting, cough, tummy pain, diarrhoea, frequent wee, constipation, sweating, hair loss, weight change, vaginal bleeding/discharge. More serious side effects include allergic reaction i.e. wheezing, difficulty breathing, swelling of lips, tongue/face, blisters/spreading rash on eyes, lips, face; yellow eyes/skin, unable to wee; loss of vision, balance, co-ordination; difficulty speaking, confusion, constant flu-like symptoms i.e. fever, chills, sore throat; bluish/pale skin, heart palpitations, irregular/fast heartbeat, crushing chest pain, numb/tingling limbs, bone fracture.

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.

# FEMARA® (Feh-MAH-ra)

Active ingredient(s): *letrozole* (leh-TRO-zole)

## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

### 1. Why am I taking FEMARA?

**FEMARA contains the active ingredient letrozole.**

FEMARA belongs to a class of medicines called 'aromatase inhibitors'. It is also commonly referred to as an "antioestrogen."

**FEMARA is used to treat breast cancer in women who no longer have a period (post-menopause) because of natural aging, surgery or by some other means. FEMARA reduces the amount of a hormone (chemical) known as 'oestrogen' that your body produces naturally to reduce the spread of cancer.**

### 2. What should I know before I take FEMARA?

#### Warnings

**Do not take FEMARA if:**

- you are allergic to letrozole, 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 are still having your period (pre-menopause).
- you are pregnant or are breast-feeding.
- the expiry date printed on the packaging has passed.
- the packaging is torn or shows signs of tampering.

**Check with your doctor if you:**

- have a liver condition.
- have a problem with your kidneys.
- have a history of bone fractures or brittle bones from reduce bone mass ('osteoporosis').
- are allergic to any other medicines, dyes, or preservatives.

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?](#)

#### Screening

FEMARA can only be taken in women who are no longer having periods.

Your doctor may send you for a blood test to check your hormone levels and confirm this.

#### Monitoring during treatment

Your doctor may want to check on your bones during treatment using a bone density test or may send you for an X-ray.

Your doctor may also send you for blood tests from time to time to check how your heart, liver and kidneys are doing while taking FEMARA, especially if you have a known condition affecting these. Your doctor may alter your treatment plan or ask you to stop taking it depending on the results.

#### Birth control

If you have recently entered menopause or are in the early stages of menopause, your doctor will discuss contraception options with you if you are able to become pregnant. You should not become pregnant while taking FEMARA as it might harm your unborn baby.

#### Male patients

FEMARA may reduce fertility in men.

#### Pregnancy and breastfeeding

Tell your doctor straight away if you are pregnant or intend to become pregnant. There are reports of abnormalities in babies born to mothers who took FEMARA during pregnancy.

You must not take FEMARA if you are breastfeeding or intend to breastfeed. It may pass into your breast milk and harm your baby.

### 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 FEMARA and affect how it works.**

**Medicines that may increase the effect of FEMARA include:**

- Anti-fungal medicines such as ketoconazole, itraconazole, voriconazole
- Medicines for HIV such as ritonavir
- Antibiotics such as clarithromycin, and telithromycin
- Methoxsalen used for some skin conditions

**Medicines that may reduce the effect of FEMARA include:**

- Medicines for seizures (fits) such as phenytoin or phenobarbital
- Clopidogrel which you may be taking if you have had previously had a heart attack or a stroke.
- Some antibiotics like rifampicin.
- Some other breast cancer medicines such as carbamazepine or tamoxifen.

- St. John's wort (a herbal extract) used in a variety of conditions.
- Other medicines that contain oestrogen or affect the amount of oestrogen in your body.

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

**Your doctor may consider your treatment carefully if you are taking any of these medicines.**

## 4. How do I take FEMARA?

### How much to take

- The usual dose is one (1) FEMARA tablet a day.
- Follow the instructions provided by your doctor and take FEMARA until your doctor tells you to stop.

### How to take FEMARA

- Swallow the tablet whole with a glass of water or other liquid.
- If your tummy is upset after you take the tablet you can take FEMARA with a meal or after a snack.

### When to take FEMARA

- FEMARA should be used regularly at the same time each day to help you remember to take it.

### How long to take FEMARA

- Take FEMARA for as long as your doctor tells you to.

### If you forget to take FEMARA

**If you miss your dose at the usual time and it is almost time for your next tablet (in the next 2-3 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise, take your tablet as soon as you remember and then go back to taking the tablet as you normally would.**

**Do not take two tablets to make up for the dose you missed.**

### If you take too much FEMARA

If you think that you have used too much FEMARA, 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 taking FEMARA?

### Things you should do

- Remind any doctor, dentist, or pharmacist you visit that you are taking FEMARA.
- Keep all your doctor's appointments so that your progress can be checked.

- Promptly get all blood tests, bone tests and any other tests on your liver, heart or kidneys done so that your doctor can check these.
- Use birth control to avoid becoming pregnant.

### Call your doctor straight away if you:

- Become pregnant or think you may be pregnant.
- Are experiencing an allergic reaction to the medicine.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin; swelling of the face, lips, tongue, or other parts of the body; shortness of breath, wheezing or trouble breathing.

### Things you should not do

- Do not stop taking this medicine suddenly.
- Do not give FEMARA to someone else.

### Driving or using machines

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

FEMARA can make you feel tired or dizzy. You must not drive or operate machinery if you are experiencing this.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

FEMARA can make you feel tired or dizzy. Alcohol may increase the effect.

### Looking after your medicine

- Keep FEMARA tablets inside the original packaging until it is time to take them.

Store it in a cool dry place below 30°C (room temperature) 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 windowsills.

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

### When to discard your medicine

**You must only discard your medicine if your doctor has told you to stop taking it or the expiry date on the packaging has passed.**

### 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 or if the packaging is torn or shows signs of tampering.

## 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>Tummy problems:</b> <ul style="list-style-type: none"> <li>Constipation or diarrhoea</li> <li>Indigestion or discomfort/pain</li> <li>Throwing up (vomiting)</li> </ul> <b>Vaginal problems:</b> <ul style="list-style-type: none"> <li>Spotting or bleeding</li> <li>Dryness/thick, white discharge</li> </ul> <b>General well-being:</b> <ul style="list-style-type: none"> <li>Feeling sick (nausea), tired (fatigue) or weak</li> <li>Cough, headache</li> <li>Trouble sleeping (insomnia) or feeling sleepy (drowsy)</li> <li>Sweating, feeling thirsty</li> <li>Changes to appetite or weight</li> <li>Hair loss</li> <li>Feeling anxious, nervous, annoyed, or sad</li> <li>Trouble remembering things</li> </ul> <b>Skin/soft tissue problems:</b> <ul style="list-style-type: none"> <li>Dry, itchy, red, irritated skin/eyes</li> <li>Hot flushes</li> <li>Dry or sore mouth, ulcers (mouth sores), cold sores</li> </ul> <b>Signs of urinary tract infection:</b> <ul style="list-style-type: none"> <li>Pain when going to the toilet</li> <li>Going to the toilet more often</li> </ul> <b>Muscle or joint problems:</b> <ul style="list-style-type: none"> <li>Back/breast/muscle/joint pain</li> <li>Pain in arms and legs, stiffness</li> <li>Arthritis, carpal tunnel, or trigger finger (finger bent and stuck)</li> </ul> <b>Balance problems:</b> <ul style="list-style-type: none"> <li>Feeling dizzy, vertigo, falls</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<b>Heart problems:</b> <ul style="list-style-type: none"> <li>Fast or irregular heartbeat</li> <li>Increased blood pressure</li> <li>Crushing chest pain or sudden shooting arm or leg (foot) pain (signs of a heart attack)</li> </ul> <b>Signs of an allergic reaction:</b> <ul style="list-style-type: none"> <li>Trouble breathing, wheezing</li> <li>Spreading rash, red skin, blistering of the lips, eyes or mouth, skin peeling (signs of skin disorder)</li> <li>Swelling of the face and throat.</li> </ul> <b>Liver and kidney problems:</b> <ul style="list-style-type: none"> <li>Yellow skin or eyes (jaundice)</li> <li>Very dark wee or unable to wee</li> </ul> <b>Vision problems:</b>	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>Blurry vision (cataract) or blindness</li> </ul> <b>Blood or circulation problems:</b> <ul style="list-style-type: none"> <li>Weakness or being unable to move limbs or face, difficulty speaking/slurred speech, problems balancing or moving properly (signs of stroke)</li> <li>Swelling and redness along a vein which is extremely tender, painful to touch</li> <li>Numbness or painful swelling/tingling in hands or feet, limbs</li> <li>Bluish skin, coughing up blood, fainting</li> <li>Swelling of the feet, ankles, or other parts of the body due to fluid build-up (signs of oedema)</li> </ul> <b>Infections</b> <ul style="list-style-type: none"> <li>Flu-like symptoms including fever, chills, sore throat, general lack of energy or tiredness</li> <li>Feeling constantly sick, sores in mouth</li> </ul> <b>Bone problems:</b> <ul style="list-style-type: none"> <li>Thinning of bones (osteoporosis), bone fractures</li> </ul>	

**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.

FEMARA is available in tablets containing 2.5 mg of the active ingredient, letrozole.

### What FEMARA contains

<b>Active ingredient (main ingredient)</b>	letrozole
<b>Other ingredients (inactive ingredients)</b>	silica - colloidal anhydrous cellulose - microcrystalline lactose magnesium stearate starch-maize sodium starch glycollate

	hypromellose iron oxide yellow macrogol 8000 talc - purified titanium dioxide
<b>Potential allergens</b>	Contains lactose, galactose, milk, sulfites, sugars, and ethanol.

Femara does not contain sucrose, gluten, tartrazine, or any other azo dyes.

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

#### **What FEMARA looks like**

FEMARA 2.5 mg tablets: dark yellow, round, coated tablet, marked 'CG' on one side and 'FV' on the other; supplied in blister packs in a cardboard carton of 30 tablets (AUST R 60605).

#### **Who distributes FEMARA**

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113 Australia

Telephone 1-800-671-203

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