

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 taking FEMOLET?

FEMOLET contains the active ingredient letrozole. FEMOLET is used to treat breast cancer in post-menopausal women.

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

2. What should I know before I take FEMOLET?

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.

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

3. What if I am taking other medicines?

Some medicines may interfere with FEMOLET 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 FEMOLET?

- The usual dose is one FEMOLET tablet every day.
- Always swallow your tablet whole with a glass of water or other liquid.

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

5. What should I know while taking FEMOLET?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using FEMOLET. • If you become pregnant while taking FEMOLET, tell your doctor immediately. • Be sure to keep all your appointments with your doctor so your progress can be checked.
Things you should not do	• Do not stop using this medicine suddenly. • Do not use FEMOLET to treat any other conditions unless your doctor tells you to. • Do not give FEMOLET to anyone else.
Driving or using machines	• FEMOLET may occasionally cause drowsiness, dizziness or other symptoms, which could affect your ability to drive or operate machinery.
Drinking alcohol	• FEMOLET may cause drowsiness or dizziness. Alcohol may increase this effect.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C. Store in original container.

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

6. Are there any side effects?

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, stomach pain, diarrhoea, frequent urination, 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 urinate; 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, swelling and redness along a vein, bone fracture, tendonitis, pain or swelling around joints, tendon tears.

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.

FEMOLET[®]

Active ingredient(s): *letrozole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FEMOLET. 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 FEMOLET.

Where to find information in this leaflet:

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

1. Why am I taking FEMOLET?

FEMOLET contains the active ingredient letrozole.

FEMOLET belongs to a family of medicines called aromatase inhibitors. They are also called "antioestrogens" because they act by reducing the production of oestrogen in your body.

Oestrogen stimulates the growth of certain types of breast cancer. These cancers are called "oestrogen-dependent". Reducing the production of oestrogen may help to keep the cancer from growing.

FEMOLET is used to treat breast cancer in women who are post-menopausal, or in other words, women who no longer have periods, either naturally due to their age or after surgery or chemotherapy.

2. What should I know before I take FEMOLET?

Warnings

Do not take FEMOLET 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 periods. This medicine is only used in women who are no longer having periods.

Women of child-bearing age who recently became postmenopausal or perimenopausal should use a proven method of birth control to avoid pregnancy, until your postmenopausal status is fully established.

Ask your doctor about options of effective birth control.

Your doctor may send you for a blood test to check your hormone levels and confirm you are no longer having periods.

- **you are male.**

Men are not normally treated with FEMOLET as it may reduce fertility in male patients.

- **the person you intend to give this medicine to is a child.**

FEMOLET is not recommended for use in children.

Check with your doctor if you:

- **have a kidney or liver condition.**
Your doctor may want to take special precautions while you are taking this medicine if you have any of these conditions.
- have a history of bone fractures or brittle bones from reduced bone mass (a condition called osteoporosis). Your doctor may want to check on your bones during treatment using a bone density test or may send you for an X-Ray.
- **are allergic to any other medicines, foods, dyes or preservatives.**
Your doctor will want to know if you are prone to allergies.

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

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

Your doctor will discuss with you the potential risks of taking FEMOLET during pregnancy. There are reports of abnormalities in babies born to mothers who took FEMOLET during pregnancy.

Talk to your doctor 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 FEMOLET and affect how it works.

Medicines that may affect FEMOLET include:

- anti-fungal medicines such as ketoconazole, itraconazole, voriconazole
- medicines for HIV such as ritonavir
- antibiotics such as clarithromycin, and telithromycin
- methoxsalen which is used for some skin conditions
- 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 FEMOLET.

4. How do I take FEMOLET?

How much to take

- The usual dose is one FEMOLET tablet every day.
- **Follow the instructions provided and use FEMOLET until your doctor tells you to stop.**
Your doctor will check your progress to make sure the medicine is working and will decide how long your treatment should continue.

How to take FEMOLET

- **Always swallow the tablet whole with a glass of water or other liquid.**
You can take the tablet with or without food.
- **If your stomach is upset after taking the tablet, take it with a meal or after a snack.**

When to take FEMOLET

- **Take FEMOLET at about the same time each day.**
Taking your tablet at about the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to take FEMOLET

If you miss your dose at the usual time and it is almost time for your next dose (e.g. within 2 or 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the dose as soon as you remember, and then go back to taking your tablet as you would normally.

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

If you miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

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

If you take too much FEMOLET

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 FEMOLET?

Things you should do

Tell your doctor immediately if you become pregnant while taking FEMOLET.

Your doctor needs to know immediately so that FEMOLET can be replaced by another medicine. You should not take this medicine while you are pregnant. Use birth control to avoid pregnancy, until your postmenopausal status is fully established.

Call your doctor straight away if you 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.

Follow your doctor's instructions carefully.

If you do not follow your doctor's instructions, your treatment may not help or you may have unwanted side effects.

Be sure to keep all your appointments with your doctor so your progress can be checked.

Your doctor may want you to have blood tests from time to time to check on your progress and detect any unwanted side effects. Your doctor may also decide to monitor your bone health as this medicine may cause thinning or wasting of your bones (osteoporosis).

Before starting any new medicine, tell your doctor, dentist or pharmacist that you are taking FEMOLET.

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

If you go into hospital, please let the medical staff know that you are taking FEMOLET.

Things you should not do

- Do not take FEMOLET for a longer time than your doctor has prescribed.
- Do not let yourself run out of FEMOLET over the weekend or on holidays.
- Do not stop taking this medicine suddenly.
- Do not use FEMOLET to treat any other conditions unless your doctor tells you to.
- Do not give FEMOLET to anyone else, even if their symptoms seem to be similar to yours.

Driving or using machines

Be careful before you drive, use any machines or tools or do jobs that require you to be alert until you know how FEMOLET affects you.

FEMOLET may occasionally cause drowsiness, dizziness or other symptoms, which could affect your ability to drive or operate machinery. Make sure you know how you are affected by this medicine before you drive or use machinery.

Drinking alcohol

FEMOLET can make you drowsy or dizzy. Alcohol may increase the effect.

Looking after your medicine

- **Keep your tablets in the original pack until it is time to take them.**
If you take the tablets out of the pack they will not keep well.
- **Keep your tablets in a cool dry place where the temperature stays below 25°C. Store in original container.**

Follow the instructions in 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.
- Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If your doctor tells you to stop taking FEMOLET, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

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
• Stomach Problems: • Constipation or diarrhoea • Indigestion or discomfort/pain	Speak to your doctor if you have any of these less serious side effects and they worry you.
Vaginal Problems:	

Less serious side effects	What to do
• Spotting or bleeding • Dryness • Thick, whitish discharge	
General Well-Being:	
• Feeling sick (nausea or vomiting) • High cholesterol • Cough, headache • Trouble sleeping (insomnia) or feeling sleepy (drowsy) • Increased sweating or thirst • Changes to appetite or weight • Hair loss • Feeling anxious, nervous, annoyed or sad • Trouble remembering things	
Skin/Soft Tissue Problems:	
• Dry, itchy, red, irritated skin or eyes • Hot flushes • Dry or sore mouth, ulcers (mouth sores), cold sores	
Bladder Problems:	
• Urgent need to urinate (pass water) • Pain or burning sensation when urinating, which may be a sign of an urinary tract infection	
Muscle or Joint Problems:	
• Back/breast/muscle/joint pain • Pain in arms and legs, stiffness • Arthritis, carpal tunnel, or trigger finger (finger bend and stuck)	
Balance Problems:	
• Feeling dizzy, vertigo, falls	

Serious side effects

Serious side effects	What to do
• Heart Problems: • Fast or irregular heartbeat • Increased blood pressure • Crushing chest pain or sudden shooting arm or leg (foot) pain (signs of a heart attack)	Call your doctor straight away, or go straight to the Emergency Department at your nearest

Serious side effects	What to do
Signs of an Allergic Reaction: • Trouble breathing, wheezing • Spreading rash, red skin, blistering of lips, eyes or mouth, skin peeling (signs of skin disorder) • Swelling of the face or throat Liver and Kidney Problems: • Yellow skin or eyes (jaundice) • Very dark urine or unable to urinate Vision Problems: • Blurry vision (cataract) or blindness Blood or Circulation Problems: • Weakness or being unable to move limbs or face, difficulty speaking/slurred speech, problems balancing or moving properly (signs of stroke) • Swelling and redness along a vein which is extremely tender or painful to touch (signs of thrombophlebitis) • Numbness or painful swelling/tingling in hands or feet, limbs • Bluish skin, coughing up blood, fainting • Swelling of the feet, ankles or other parts of the body due to fluid build-up (signs of oedema) Infections: • Flu-like symptoms including fever, chills, sore throat, general lack of energy or tiredness • Feeling constantly sick, sores in mouth Bone and Connective Tissue Problems: • Thinning of bones (osteoporosis), bone fractures • Tendon disorders including tendonitis (inflammation of the tendon) and tenosynovitis (inflammation of the tissue surrounding the tendon): pain, swelling and tenderness near a joint • Tendon tears: feeling a snap or pop when the tear happened, severe pain, swelling	hospital if you notice any of these serious side effects.

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. 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 FEMOLET contains

Active ingredient (main ingredient)	Letrozole 2.5 mg
Other ingredients (inactive ingredients)	• Colloidal anhydrous silica • Microcrystalline cellulose • Lactose monohydrate • Magnesium stearate • Maize Starch • Sodium starch glycollate • OPADRY II complete film coating system 40L38238 YELLOW (ARTG PI No: 107043).
Potential allergens	Contains lactose, sulfites and trace amounts of phenylalanine.

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

What FEMOLET looks like

FEMOLET is a 2.5 mg dark yellow, capsule-shaped, slightly biconvex film-coated tablet debossed with "LZ 2.5" on one side and "G" on the other side. (AUST R 166010).

FEMOLET comes in blister packs containing 30 tablets.

Who distributes FEMOLET

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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FEMOLET® is a Viatris company trade mark

