

FEMOLET®

contains the active ingredient letrozole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FEMOLET.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.mylan.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FEMOLET against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What FEMOLET is used for

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.

Letrozole, the active ingredient in 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.

This may be the first time you are taking an "antioestrogen" such as FEMOLET or you may have taken another "antioestrogen" such as tamoxifen in the past.

Follow all directions given to you by your doctor.

They may differ from the information contained in this leaflet.

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

Your doctor may have prescribed FEMOLET for another reason.

FEMOLET is only available with a doctor's prescription.

FEMOLET is not addictive.

Before you take FEMOLET

When you must not take it

Do not take FEMOLET if you are allergic to:

- letrozole, the active ingredient of FEMOLET
- any of the other ingredients of FEMOLET, as listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include skin

rash, itching or hives on the skin; swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing; swelling to other parts of the body; wheezing, troubled breathing or shortness of breath.

Do not take FEMOLET if 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.

Do not take FEMOLET if you are pregnant or breast-feeding. 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."

It may affect your baby if you take it whilst you are pregnant or breast feeding.

Do not take FEMOLET if you are male.

Men are not normally treated with FEMOLET.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or show signs of tampering.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Do not give FEMOLET to a child. FEMOLET is not recommended for use in children.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

Tell your doctor if you have severe kidney or liver disease.

Your doctor may want to take special precautions while you are taking this medicine if you have any of these conditions.

Tell your doctor if you are pregnant or planning to become pregnant.

If you have not told your doctor about any of the above, tell him/her before you start taking FEMOLET.

Taking other medicines

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

Other medicines may be affected by FEMOLET or they may affect how well it works.

Your doctor or pharmacist can tell you what to do when taking FEMOLET with other medicines.

This includes in particular:

- tamoxifen.
- other anti-estrogens or estrogen-containing therapies.

These substances may diminish the action of Femolet.

Females of child-bearing potential and male patients.

If you still until recently had menstrual periods, you should discuss with your doctor about the necessity of effective contraception as you might have the potential to become pregnant. Ask your doctor about options of effective birth control.

Femolet may reduce fertility in male patients.

How to take FEMOLET

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 pack, ask your doctor or pharmacist for help.

How to take it

Always swallow the tablets whole with a glass of water or other liquid.

You can take the tablets with or without food.

If your stomach is upset after taking the tablet, take it with a meal or after a snack.

How much to take

The usual dose is one FEMOLET tablet every day.

When to take it

Take your FEMOLET at about the same time each day.

Taking your tablet(s) at about the same time each day will have the best effect. It will also help you remember when to take the tablets.

How long to take it for

Keep taking FEMOLET for as long as your doctor tells you to.

Your doctor will check your progress to make sure the medicine is working and will decide how long your treatment should continue.

If you are unsure, talk to your doctor.

If you forget to take it

If 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 (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much FEMOLET. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy. You may need urgent medical attention.

While you are taking FEMOLET

Things you must do

If you become pregnant while taking FEMOLET, tell your doctor immediately.

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.

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 must 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 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.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking FEMOLET until you know how it 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FEMOLET.

It may have unwanted side effects in some people in addition to its beneficial effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. Side effects may happen at the start of treatment or they may happen after you have been taking your medicine for some time. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood, rapid heartbeat, bluish skin discolouration,
- constant "flu-like" symptoms (chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy) that could be a sign of blood problems.
- swelling mainly of the face and throat (signs of allergic reaction)
- weakness or paralysis of limbs or face, difficulty speaking (signs of stroke)
- crushing chest pain or sudden arm or leg (foot) pain (signs of a heart attack)
- swelling and redness along a vein which is extremely tender possibly painful to touch (signs of thrombophlebitis)

The above side effects may be serious. You may need urgent medical attention or hospitalisation. Tell your doctor straight away if you experience any of the following:

- yellow skin and eyes, nausea, loss of appetite, dark coloured urine (signs of hepatitis)
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder) blurred vision (sign of cataract)
- swelling of the feet, ankles or other parts of the body due to fluid build-up (signs of oedema)

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:

- swelling of the feet, ankles or other parts of the body due to fluid build up
- skin rash, itching or dry skin
- pain in the muscles, joints or bones; joint stiffness, arthritis, back pain
- high level of cholesterol
- vaginal spotting or bleeding
- whitish, thick vaginal discharge, vaginal dryness
- headache
- fever
- tiredness, sleepiness, weakness or dizziness, vertigo
- fall
- chest pain
- difficulty sleeping
- drowsiness
- numbness or tingling in the hands or feet
- carpal tunnel syndrome
- mood changes such as anxiety, nervousness, irritability and depression (sad mood)
- forgetfulness
- blurred vision or eye irritation
- stomach upset, nausea (feeling sick) or vomiting, pain in the abdomen

- constipation
- diarrhoea
- thirst, change in sense of taste, dry mouth
- dry mouth, sore mouth, mouth ulcers and cold sores
- increased thirst
- breast pain
- hot flushes
- increased sweating
- appetite or weight changes
- hair thinning
- urgent need to urinate (pass water)
- pain or burning sensation when urinating, which may be a sign of an infection
- fast or irregular heartbeat, palpitations, high blood pressure (hypertension)
- cough
- yellowish eyes and/or skin (jaundice)
- thinning of bones (osteoporosis), bone fractures
- locking of the finger and pain (trigger finger)

The above side effects may be serious. You may require urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some of these can only be found by laboratory testing.

After taking FEMOLET

Storage

Keep FEMOLET 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.

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.

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

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

Heat and dampness can destroy some medicines.

Disposal

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.

Product description

What it looks like

FEMOLET is available in 1 tablet strength:

- 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.

FEMOLET comes in blister packs containing 30 tablets.

Ingredients

The active ingredient in FEMOLET is letrozole.

Each FEMOLET tablet contains 2.5 mg of letrozole.

The tablets also contain the following inactive ingredients:

- Colloidal anhydrous silica
- Microcrystalline cellulose
- Lactose
- Magnesium stearate
- Maize Starch
- Sodium starch glycollate
- Iron oxide yellow
- Hypromellose
- Polydextrose

- Macrogol
- Quinoline yellow aluminium lake
- Iron oxide red
- Triacetin
- Titanium dioxide.

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

Supplier

FEMOLET is supplied by:

Alphapharm Pty Limited
(ABN 93 002 359 739)

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

FEMOLET 2.5 mg - AUST R
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