

Package leaflet: Information for the user

**FEMARA® 2.5mg Tablets
(letrozole)**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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2. What you need to know before you take Femara
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1. What Femara is and what it is used for

What Femara is and how it works

Femara contains an active substance called letrozole. It belongs to a group of medicines called aromatase inhibitors. It is a hormonal (or “endocrine”) breast cancer treatment. Growth of breast cancer is frequently stimulated by oestrogens which are female sex hormones. Femara reduces the amount of oestrogen by blocking an enzyme (“aromatase”) involved in the production of oestrogens and therefore may block the growth of breast cancer that needs oestrogens to grow. As a consequence tumour cells slow or stop growing and/or spreading to other parts of the body.

What Femara is used for

Femara is used to treat breast cancer in women who have gone through menopause i.e cessation of periods.

It is used to prevent cancer from happening again. It can be used as first treatment before breast cancer surgery in case immediate surgery is not suitable or it can be used as first treatment after breast cancer surgery or following five years treatment with tamixofen. Femara is also used to prevent breast tumour spreading to other parts of the body in patients with advanced breast cancer.

If you have any questions about how Femara works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Femara

Follow all the doctor’s instructions carefully. They may differ from the general information in this leaflet.

Do not take Femara

- if you are allergic to letrozole or to any of the other ingredients of this medicine (listed in section 6),
- if you still have periods, i.e. if you have not yet gone through the menopause,
- if you are pregnant,
- if you are breast-feeding.

If any of these conditions apply to you, **do not take this medicine and talk to your doctor.**

Warnings and precautions

Talk to your doctor or pharmacist before taking Femara

- if you have a severe kidney disease,
- if you have a severe liver disease,
- if you have a history of osteoporosis or bone fractures (see also "Follow-up during Femara treatment" in section 3).

If any of these conditions apply to you, **tell your doctor.** Your doctor will take this into account during your treatment with Femara.

Children and adolescents (below 18 years)

Children and adolescents should not use this medicine.

Older people (age 65 years and over)

People aged 65 years and over can use this medicine at the same dose as for other adults.

Other medicines and Femara

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

- You should only take Femara when you have gone through the menopause. However, your doctor should discuss with you the use of effective contraception, as you may still have the potential to become pregnant during treatment with Femara.
- You must not take Femara if you are pregnant or breast feeding as it may harm your baby.

Driving and using machines

If you feel dizzy, tired, drowsy or generally unwell, do not drive or operate any tools or machines until you feel normal again.

Femara contains lactose

Femara contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Femara

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet of Femara to be taken once a day. Taking Femara at the same time each day will help you remember when to take your tablet.

The tablet can be taken with or without food and should be swallowed whole with a glass of water or another liquid.

How long to take Femara

Continue taking Femara every day for as long as your doctor tells you. You may need to take it for months or even years. If you have any questions about how long to keep taking Femara, talk to your doctor.

Follow-up during Femara treatment

You should only take this medicine under strict medical supervision. Your doctor will regularly monitor your condition to check whether the treatment is having the right effect.

Femara may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body. Your doctor may decide to measure your bone density (a way of monitoring for osteoporosis) before, during and after treatment.

If you take more Femara than you should

If you have taken too much Femara, or if someone else accidentally takes your tablets, contact a doctor or hospital for advice immediately. Show them the pack of tablets. Medical treatment may be necessary.

If you forget to take Femara

- 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 take the next tablet as you would normally.
- Do not take a double dose to make up for the one that you missed.

If you stop taking Femara

Do not stop taking Femara unless your doctor tells you to. See also the section above “How long to take Femara”.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Some of these side effects, such as hot flushes, hair loss or vaginal bleeding, may be due to the lack of oestrogens in your body.

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

Some side effects could be serious:

Rare or uncommon side effects (i.e. they may affect between 1 to 100 in every 10,000 patients):

- Weakness, paralysis or loss of feeling in any part of the body (particularly arm or leg), loss of coordination, nausea, or difficulty speaking or breathing (sign of a brain disorder, e.g. stroke).
- Sudden oppressive chest pain (sign of a heart disorder).
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm, leg or foot pain (signs that a blood clot may have formed).
- Swelling and redness along a vein which is extremely tender and possibly painful when touched.
- Severe fever, chills or mouth ulcers due to infections (lack of white blood cells).
- Severe persistent blurred vision.

If any of the above occurs, tell your doctor straight away.

You should also inform the doctor straight away if you experience any of the following symptoms during treatment with Femara:

- Swelling mainly of the face and throat (signs of allergic reaction).
- 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).

Some side effects are very common. These side effects may affect more than 10 in every 100 patients.

- Hot flushes
- Increased level of cholesterol (hypercholesterolaemia)
- Fatigue
- Increased sweating
- Pain in bones and joints (arthralgia)

If any of these affects you severely, tell your doctor.

Some side effects are common. These side effects may affect between 1 to 10 in every 100 patients.

- Skin rash
- Headache
- Dizziness
- Malaise (generally feeling unwell)
- Gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhoea
- Increase in or loss of appetite
- Pain in muscles
- Thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also “Follow-up during Femara treatment” in section 3)
- Swelling of arms, hands, feet, ankles (oedema)
- Depression

- Weight increase
- Hair loss
- Raised blood pressure (hypertension)
- Abdominal pain
- Dry skin
- Vaginal bleeding

If any of these affects you severely, tell your doctor.

Other side effects are uncommon. These side effects may affect between 1 to 10 in every 1,000 patients.

- Nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, somnolence, insomnia
- Impairment of sensation, especially that of touch
- Eye disorders such as blurred vision, eye irritation
- Palpitations, rapid heart rate
- Skin disorders such as itching (urticaria)
- Vaginal discharge or dryness
- Joint stiffness (arthritis)
- Breast pain
- Fever
- Thirst, taste disorder, dry mouth
- Dryness of mucous membranes
- Weight decrease
- Urinary tract infection, increased frequency of urination
- Cough
- Increased level of enzymes

If any of these affects you severely, tell your doctor.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Femara

Store the tablets in their original pack. Do not store above 30°C.

Keep all medicines out of the reach and sight of children.

Do not take the tablets after their expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking Femara, please take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Contents of the pack and other information

What Femara contains

- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
- The other ingredients are silica aerogel, cellulose, lactose, magnesium stearate, maize starch, sodium carboxymethyl starch, hydroxypropyl methylcellulose, polyethylene glycol, talc, titanium dioxide (E171) and iron oxide yellow (E172).

What Femara looks like and contents of the pack

Femara Tablets are round, yellow tablets marked FV on one side and CG on the other.

They come in blister packs of 14, 28 or 30. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Novartis Pharmaceuticals UK Limited, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, United Kingdom.

Manufacturer

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This leaflet was last revised in May 2013.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, telephone number 01276 698370.

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