Package Leaflet: Information for the User

Femara® 2.5 mg film-coated tablets

(letrozole)

Your medicine is known by the above name, but will be referred to as Femara® throughout this leaflet.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Femara® is and what it is used for
2. What you need to know before you take Femara®
3. How to take Femara®
4. Possible side effects
5. How to store Femara®
6. Contents of the pack and other information

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 tamoxifen. 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, pharmacist or nurse 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®.

Letrozole may cause inflammation in tendons or tendon injury (see section 4). At any sign of tendon pain or swelling – rest the painful area and contact your doctor.

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Femara® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium free”.

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.

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 your 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:

Uncommon (may affect up to 1 in 100 people):

- 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).
- 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.
- Inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones).

Rare (may affect up to 1 in 1,000 people):

- 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).
- Rupture of a tendon (connective tissues that connect muscles to bones)

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 (may affect more than 1 in 10 people):

- 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 (may affect up to 1 in 10 people):

- 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
- Palpitations, rapid heart rate
- Joint stiffness (arthritis)
- Chest pain

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

Other side effects are uncommon (may affect up to 1 in 100 people):

- Nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, somnolence, insomnia
- Pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- Impairment of sensation, especially that of touch
- Eye disorders such as blurred vision, eye irritation
- Skin disorders such as itching (urticaria)
- Vaginal discharge or dryness
- 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
- Yellowing of the skin and eyes
- High blood levels of bilirubin (a breakdown product of red blood cells)

Side effects with frequency not known

(frequency cannot be estimated from the available data)

Trigger finger, a condition in which your finger or thumb locks in a flex position.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE FEMARA®

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package in order to protect from moisture.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures 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 lactose monohydrate, cellulose microcrystalline, maize starch, sodium starch glycolate, magnesium stearate and silica colloidal anhydrous.
- The coating is composed of hypromellose, talc, macrogol 8000, titanium dioxide (E 171) and iron oxide yellow (E 172).

What Femara® looks like and contents of the pack

Femara® is supplied as film-coated tablets. The tablets are dark-yellow and round. They are marked with “FV” on one side and “CG” on the other side.

Each blister pack contains 30 tablets.

Manufactured by Novartis Farma S.p.A, Via Provinciale Schito 131, 80058 Torre Annunziata NA, Italy.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

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