

FEMARA[®] FILM-COATED TABLET

Letrozole (2.5mg)

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What Femara is used for

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.

Femara is used to treat breast cancer in women who are post-menopausal – that is, women who no longer have periods, either naturally due to their age or after surgery or chemotherapy. It is also used before surgery in postmenopausal breast cancer women.

How Femara works

Growth of breast cancer is often stimulated by estrogens, which are female sex hormones. Femara reduces the amount of estrogen by blocking an enzyme (“aromatase”) involved in the production of estrogens and therefore, may block the growth of breast cancers that need estrogen to grow. As a consequence tumor cells slow or stop the progression and/or spreading to other parts of the body.

Before you use Femara

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

- When you must not use it

- If you are allergic (hypersensitive) to letrozole or to any of the ingredients in Femara listed in this leaflet. If you think you may be allergic, ask your doctor for advice.
- 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, tell your doctor before taking Femara.

Pregnancy

You must not take Femara if you are pregnant as it may harm your unborn baby. Your doctor will discuss with you the potential risks of taking Femara during pregnancy. There are reports of abnormalities in babies born to mothers who took Femara during pregnancy.

Since Femara is only recommended for postmenopausal women, pregnancy restrictions most likely will not apply to you.

Breast-feeding

Do not breast-feed during your treatment with Femara. Tell your doctor if you are breast-feeding.

Information about some of the ingredients of Femara

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

-Before you start to use it

- If you have a severe kidney disease.
- If you have a severe liver disease.
- If you have a history of osteoporosis or bone fractures.

Your level of hormones may be checked by your doctor before you take Femara to ensure you have gone through the menopause (cessation of periods).

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

Older people (age 65 years and over)

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

Children and adolescents (below 18 years)

Femara is not to be used in children or adolescents.

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. Use effective birth control during treatment.

Ask your doctor about options of effective birth control.

If you recently became postmenopausal or if you are near to having menopause, you should discuss with your doctor about the necessity of contraception as you might have the potential to become pregnant.

-Taking other medicines

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- Tamoxifen.
- Ketoconazole, itraconazole, voriconazole
- Ritonavir
- Clarithromycin, telithromycin and rifampicin
- Methoxsalen
- Phenytoin, carbamazepine, phenobarbital
- St. John’s Wort
- Clopidogrel
- Other anti-estrogens or estrogen-containing therapies.

These substances may diminish the action of Femara.

How to use Femara

Always take Femara exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

-How much to use

The usual dose is one tablet of Femara to be taken once a day.

-When to use Femara

Taking Femara at the same time each day will help you remember when to take your tablet.

The tablet should be swallowed whole with a glass of water or another liquid.

-How long to use Femara

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

-If you forget to use Femara

- If it is almost time for your next dose, 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 use too much (overdose)

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

While you are using Femara

-Things you must do

Take your medicine exactly as your doctor has told you.

-Things you must not do

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

-Things to be careful of

Driving and using machines

If you feel dizzy or drowsy, or if you experience blurred vision, do not drive or operate any tools or machines until you feel normal again.

Monitoring during your Femara treatment

Femara should only be taken under strict medical supervision. Your doctor will regularly monitor your condition to check if the treatment is having the desired effect.

Your doctor may also decide to monitor your bone health as this medicine may cause thinning or wasting of your bones (osteoporosis).

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

Side effects

As with all medicines, individual taking Femara may experience 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 them, such as hot flushes, hair loss or vaginal bleeding may be due to the lack of estrogens in your body. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Side effects may occur with certain frequencies, which are defined as follows:

Very common:	affects more than 1 in 10 people
Common:	affects between 1 and 10 in every 100 people

Side effects that can be serious

- Weakness or paralysis of limbs or face, difficulty speaking (signs of stroke).
- Crushing chest pain or sudden arm or leg (foot) pain (signs of heart disorder such as heart attack).
- Swelling and redness along a vein which is extremely tender and possibly painful when touched (signs of thrombophlebitis).
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration (signs of blood clot formation such as pulmonary embolism).
- Swelling of arms, hands, feet, ankles or other part of the body (signs of edema).
- Swelling mainly of the face and throat (signs of allergic reaction).
- Blurred vision (sign of cataract).
- Yellow skin and eyes, nausea, loss of appetite, dark-colored urine (signs of hepatitis).
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder).

If you experience any of these, tell your doctor straight away.

Very common side effects

- Increased level of cholesterol
- Hot flushes
- Increased sweating
- Tiredness (including weakness generally feeling unwell)
- Pain in joints

Common side effects

- Headache
- Rash
- Dizziness, spinning sensation
- Gastrointestinal disorders, such as nausea, vomiting, indigestion, constipation, diarrhea, abdominal pain
- Increase in or loss of appetite
- Thinning or wasting of your bones (osteoporosis) leading to bone fractures in some cases
- Depression
- Weight increase

- Hair loss
- Vaginal bleeding
- Dry skin
- Raised blood pressure
- Back, bone or muscle pain
- Fall
- Strong pounding of heart beat
- Joint inflammation
- Chest pain

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

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Femara

- Storage

- Do not use after the expiry date which is stated on the carton 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.
- Do not use any pack that is damaged or shows signs of tampering.
- Keep out of the reach and sight of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

- Femara is supplied as film-coated tablets. The film-coated tablets are dark-yellow, round and slightly biconvex with bevelled edges. They are marked with "FV" on one side and "CG" on the other side.
- Femara is supplied in blister. Each blister pack contains 30 tablets.

-Ingredients

- Active ingredients

- The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.

- Inactive ingredients

- 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).

-MAL Number

MAL19973303ARZ

Manufacturer

Novartis Farma S.p.A, Torre
Annunziata, Italy.

Product Registration Holder

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