NOVARTIS

FEMARA

(Letrozole)

2,5 mg film-coated tablets

Patient Information Leaflet

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SCHEDULING STATUS: S4

FEMARA ® 2,5 mg film-coated tablets

Letrozole

Contains sugar (lactose)

Read all of this leaflet carefully before you start taking FEMARA

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.**
- **FEMARA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**
- **If you get any side effects, talk to your doctor, pharmacist, nurse or other healthcare provider. This includes any possible side effects not listed in this leaflet (see section 4).**

What is in this leaflet

6. Contents of the pack and other information

1. What FEMARA is and what it 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. 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.

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. The instructions may differ from the general information contained 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 have liver problems
- If you have kidney problems
- If you are pregnant or planning to become 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

If any of the following apply to you, tell your doctor or pharmacist or healthcare provider before taking FEMARA:

- If you have severe kidney disease.
- If you have severe liver disease
- If have osteoporosis or bone fractures
- If you are premenopausal
- If you are taking any other oestrogen containing medication

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:

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Before you take FEMARA tell your doctor or pharmacist or healthcare provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because these might interact with FEMARA. This includes, in particular:

- Do not take FEMARA with medicines that increase the concentration of FEMARA such as ketoconazole, itraconazole, voriconazole, ritonavir, clarithromycin or telithromycin.
- Do not take FEMARA with medicines that decreases the concentration of FEMARA such as phenytoin, rifampicin, carbamazepine, phenobarbital and St John's Wort.
- The use of tamoxifen with FEMARA can reduce the concentration of FEMARA.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

FEMARA TABLETS with food

FEMARA can be taken with or without food.

Pregnancy, breastfeeding 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

FEMARA may cause dizziness and drowsiness. You should not drive or use machines when you are feeling dizzy and drowsy.

Important information about some of the ingredients of FEMARA:

FEMARA contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take FEMARA.

3. How to take FEMARA

Do not share medicines prescribed for you with any other person.

Always take FEMARA exactly as your doctor has told you. You should 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.

Your doctor will tell you how long your treatment with FEMARA will last. Do not stop treatment early. If you have the impression that the effect of FEMARA is too strong or too weak, tell your doctor or pharmacist.

How long to take FEMARA

Continue taking FEMARA every day for as long as your doctor tells you.

If you have questions about how long to take FEMARA talk to your doctor or your pharmacist or healthcare provider.

If you take more FEMARA than you should

If you have accidentally taken too many tablets, **talk to your doctor**.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

FEMARA can have side effects.

Not all side effects reported for FEMARA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FEMARA, please consult your doctor, pharmacist or other health care professional for advice.

Some side effects could be serious:

- Weakness, loss of feeling in any part of your body or paralysis of limbs or face, difficulty speaking or breathing (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 discolouration (signs of blood clot formation such as pulmonary embolism).
- Swelling of arms, hands, feet, ankles or other part of the body (signs of oedema).
- Swelling mainly of the face and throat (signs of allergic reaction).
- Severe fever, chills or mouth ulcers due to infections (signs of low level of white blood cells).
- Blurred vision (sign of cataract).
- 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).

If any of the above happens, stop taking FEMARA and tell your doctor immediately or go to the casualty department at your nearest hospital.

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

Very frequent side effects

- Increased level of cholesterol (hypercholesterolemia)
- Hot flushes
- Increased sweating
- Fatigue [including weakness and malaise (generally feeling unwell)]
- Pain in bones and joints (arthralgia)

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

Frequent side effects:

- Headache
- Skin rash
- Dizziness, vertigo
- 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
- Swelling of arms, hands, feet, ankles (oedema)
- Depression
- Weight increase

- Hair loss
- Vaginal bleeding
- Dry skin
- Raised blood pressure (hypertension)
- Abdominal pain
- Back pain
- Fall
- Palpitations (rapid heart rate)
- Joint stiffness (arthritis)
- Chest pain

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

Less frequent side effects:

- Nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, insomnia
- Pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- Disturbed physical sensitivity (dysesthesia)
- Eye irritation or blurred vision
- Itchy rash (urticaria)
- Vaginal disorders such as 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
- Abnormal liver function test results (blood tests disorders)
- Increased bilirubin level (dark coloured urine)
- Jaundice (yellowish eyes and/or skin)

Frequency not known:

- Trigger finger, a condition in which your finger or thumb catches in a bent position.
- 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: feel a snap or pop when the tear happens, severe pain, swelling.

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

Reporting of side effects

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FEMARA.

5. How to store FEMARA

Store at or below 30 °C, protect from moisture.

Store in the original package

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FEMARA contains

The active ingredient is letrozole. Each film-coated tablet contains 2,5 mg letrozole.

The other ingredients are:

Colloidal anhydrous silica, microcrystalline cellulose, lactose monohydrate, magnesium stearate, maize starch, sodium starch glycollate, hydroxypropyl methylcellulose, polyethylene glycol 8000, talc, titanium dioxide, iron oxide yellow.

What FEMARA looks like and contents of the pack

What FEMARA looks like:

Dark yellow, round, slightly biconvex tablets bevelled edges. One side bears the imprint ‘FV’ and the other “CG”.

Contents of the pack:

FEMARA ® 2,5 mg tablets are packed in blister packs.

Pack sizes: 30 tablets per pack enclosed in a cardboard box.

Holder of Certificate of Registration

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