NOVARTIS

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

FEMARA®

Film-coated tablets

Composition:

Active ingredient:
Each film-coated tablet contains:
Letrozole 2.5 mg

Inactive ingredients and allergens:
See section 6 "Further Information".
See also in section 2 "Important information regarding some of the ingredients of the medicine".

Read this package insert carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Adjuvant treatment of early breast cancer in postmenopausal women.
- Extended adjuvant treatment of early breast cancer in postmenopausal women following standard adjuvant tamoxifen therapy.
- Treatment of advanced or metastatic breast cancer in postmenopausal women.
- Treatment of advanced breast cancer in postmenopausal women with disease progression following treatment with antioestrogens.

Therapeutic group: Aromatase inhibitors (antioestrogens).
This medicine is a hormonal (also called "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 may therefore block the growth of breast cancers that need oestrogen to grow. As a consequence, tumour cells slow down or stop growing and/or spreading to other parts of the body.
If you have any questions about how Femara works or why it has been prescribed for you, ask your doctor.

2. BEFORE USING THE MEDICINE

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

Do not use the medicine if:
- you are allergic (hypersensitive) to letrozole or to any of the other ingredients contained in the medicine (listed in section 6 "Further Information" in this leaflet).
- you still have menstrual periods, i.e., if you have not yet gone through menopause.
- you are pregnant.
- you are breast-feeding.

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

Special warnings regarding use of the medicine

Talk to your doctor or pharmacist before taking Femara if:
- you have severe kidney disease.
- you have severe liver disease.
- you have a history of osteoporosis or bone fractures (see also "Tests and follow-up" in section 2).

If any of these conditions apply to you, tell your doctor. Your doctor will take this information 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)
This medicine is not intended for children and adolescents under 18 years of age.

Elderly people (65 years of age and above)
Patients 65 years of age and over can use Femara at the same dosage as other adults.

Tests and follow-up
You should only take Femara 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.

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and food supplements, inform the doctor or pharmacist. Especially if you are taking:
- tamoxifen
- treatments that contain other antioestrogens or oestrogens
- phenytoin
- clopidogrel

Use of the medicine and food
The tablet can be taken with or without food.

Pregnancy, breast-feeding and fertility
- You should only take Femara if you have gone through 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 use of machines
If you feel dizzy, tired, drowsy or generally unwell, do not drive or operate any tools/machines until you feel that these effects have passed.

Important information regarding some of the ingredients of the medicine
Femara contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.
Femara contains sodium.
The amount of sodium is less than 23 mg per tablet, i.e., essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.
Check with your doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally one tablet of Femara once a day.
Do not exceed the recommended dose.

Mode of administration
Swallow the tablet whole with a glass of water. There is no information regarding crushing/splitting/chewing.
Taking Femara at the same time each day will help you remember when to take the tablet.

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

If you accidentally take a higher dosage
If you took an overdose, or if a child, or anyone else, has accidentally swallowed the medicine, immediately refer to the doctor or proceed to a hospital emergency room and bring the medicine package with you. Medical treatment may be necessary.

If you forget to take the medicine
- If it is almost time for your next dose (i.e., within 2 or 3 hours), skip the dose you missed and take your next dose at the regular time.
- 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.

Adhere to the treatment as recommended by the doctor.

If you stop taking Femara
Do not stop treatment with the medicine without consulting the doctor.
See also the section above "Duration of treatment".

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Femara may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of 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 the side effects, such as hot flushes, hair loss or vaginal bleeding may be due to the lack of oestrogens in your body.

Side effects that may be severe:

Refer to a doctor immediately if you suffer from any of the following conditions:
Uncommon side effects (effects that occur in 1-10 in 1,000 users):
- 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 side effects (effects that occur in 1-10 in 10,000 users):
- 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).

You should also inform the doctor immediately if you suffer from 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).

Additional side effects:

Very common side effects (effects that occur in more than 1 user in 10):
Hot flushes; increased level of cholesterol (hypercholesterolaemia); fatigue (including malaise [generally feeling unwell]); increased sweating; pain in bones and joints (arthralgia).
If one or more of these effects affect you severely, refer to your doctor.

Common side effects (effects that occur in 1-10 in 100 users):
Skin rash; headache; dizziness; 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 "Tests and follow-up" in section 2); swelling of arms, hands, feet and 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 one or more of these effects affect you severely, refer to your doctor.

Uncommon side effects (effects that occur in 1-10 in 1,000 users):
Nervous system 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 disorder 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 bilirubin levels (a breakdown product of red blood cells).

Side effects of unknown frequency (the frequency can not be estimated from the available data):
Trigger finger, a condition in which your finger or thumb locks in a flex position.

If one or more of these effects affect you severely, refer to your doctor.

If a side effect occurs, if any of the side effects worsen, or if you suffer from a side effect not mentioned in the leaflet you should consult your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il
Side effects can also be reported to Novartis company via the email address:
safetydesk.israel@novartis.com

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless clearly indicated by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Do not store at a temperature exceeding 30°C.
- Store in the original package to protect the tablets from moisture.
- Do not use if the package is damaged or has signs of tampering.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
  Tablet composition:
  lactose monohydrate, cellulose microcrystalline, maize starch, sodium starch glycolate, magnesium stearate and silica colloidal anhydrous.
  Coating composition:
  hypromellose, talc, macrogol 8000, iron oxide yellow (E172), titanium dioxide (E171).
  See also in section 2 "Important information regarding some of the ingredients of the medicine".
- **What does the medicine look like and what are the contents of the package**
  Femara is marketed as film-coated tablets. The film-coated tablets are round and dark yellow in colour. They are marked with "FV" on one side and "CG" on the other side.
  Femara is marketed in packages of 30 tablets.
- **Registration holder and importer and its address:**
  Novartis Israel Ltd., P.O.B. 9240, Tel Aviv.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 109 86 29281

Revised in December 2025.