PACKAGE LEAFLET: INFORMATION FOR THE USER

Eirfem 2.5 mg film coated tablets

letrozole

Rowa®
Pharmaceuticals Ltd.

The name of your medicine is Eirfem 2.5 mg film coated tablets,
which will be referred to as Eirfem tablets throughout the rest of this document.

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, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms 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. See section 4.

What is in this leaflet:

1. What Eirfem tablets are and what they are used for

Eirfem tablets contain an active substance called letrozole.
Letrozole belongs to a group of medicines called aromatase inhibitors. It is a hormonal (endocrine) breast cancer treatment.

Eirfem tablets are used to
- prevent breast cancer recurrences as first treatment after breast surgery or following five years of treatment with tamoxifen
- prevent breast tumours spreading to other parts of the body in patients in advanced stages of the disease

Eirfem tablets should be used only for oestrogen receptor-positive breast cancer and only in women after menopause (when your periods have stopped completely).

Growth of breast cancer is frequently stimulated by oestrogens, which are female sex hormones. Eirfem tablets reduce the amount of oestrogen by blocking an enzyme (aromatase) involved in the production of oestrogens. As a consequence tumour cells slow or stop growing and/or spreading to other parts of the body.
Eirfem tablets 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.
Eirfem tablets may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body (see Section 4 –Possible side effects.). Your doctor may therefore decide to measure your bone density before, during and after treatment. If you have any questions about how Eirfem tablets work or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Eirfem tablets

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

Do not take Eirfem tablets if you

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

If any of the above 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 Eirfem tablets if you have

- a severe kidney disease
- a severe liver disease
- a history of osteoporosis or bone fractures

If any of the above conditions apply to you, **tell your doctor**. Your doctor will take this into account during your treatment with Eirfem tablets.

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.

Other medicines and Eirfem tablets:

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

Children and adolescents (below 18 years)

Eirfem tablets are not to be used in children or adolescents.

EIderly (age 65 years and over)

Eirfem tablets can be used by people aged 65 years and over. The dose is the same for older people as it is for other adults.

Taking Eirfem tablets with food and drink

Eirfem tablets can be taken with or without food or a drink.

Pregnancy, breast-feeding and fertility

You must not take Eirfem tablets if you are pregnant or breast feeding as it may harm your baby. If you are pregnant or are currently breast-feeding, tell your doctor before taking Eirfem tablets. However, since Eirfem tablets are only recommended for postmenopausal women, pregnancy and breast-feeding restrictions most likely will not apply to you. However, if you recently became postmenopausal or if you are perimenopausal, your doctor should discuss with you about the necessity of a pregnancy test before taking letrozole and of a contraception as you might have the potential to become pregnant.

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.

Eirfem tablets contain sunset yellow FCF (E110)

This medicine contains sunset yellow FCF (E110). Sunset yellow FCF (E110) may cause allergic reactions.

Eirfem tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

3. How to take Eirfem tablets

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

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

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

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

Follow-up during Eirfem 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.

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

If you forget to take Eirfem tablets
- 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 Eirfem tablets
Do not stop taking Eirfem tablets unless your doctor tells you. See also the section above "Duration of treatment".

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Eirfem tablets 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 them, 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.

Serious side effects

These side effects are rare or uncommon (affect less than 1 in every 100 patients) but do require **immediate medical attention**.

- some patients experienced swelling mainly of the face and throat (signs of allergic reaction) during treatment with Eirfem tablets
- weakness, paralysis, loss of feeling in an arm or leg or any other part of the body, loss of coordination, nausea, difficulty in speaking or breathing (sign of a brain disorder, such as a stroke)
- sudden oppressive chest pain (sign of a heart disorder)
- difficulty in breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, sudden arm or leg (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 you are having any of the above, tell your doctor straight away.

<u>Other reported side effects</u>

Very common side effects

(may affect more than 1 in every 10 people)

- hot flushes
- fatigue
- increased sweating
- pain in bones and joints (arthralgia)

Common side effects

(may affect up to 1 and 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
- increased level of cholesterol (hypercholesterolaemia)
- pain in muscles
- thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also 'Follow-up during Eirfem treatment' in section 3)
- swelling of arms, hands, feet, ankles (oedema)
- sad mood (depression)
- weight Increase
- hair loss
- palpitations, rapid heart rate
- joint stiffness (arthritis)
- chest pain.

Uncommon side effects
(may affect up to 1 and 100 people)
- 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 or eye irritation
- raised blood pressure (hypertension)
- skin disorders such as itching (urticaria), dry skin
- vaginal disorders such as bleeding, discharge or dryness
- abdominal pain
- breast pain
- fever
- thirst, taste disorder, dry mouth
- dryness of mucous membranes
- weight decrease
- urinary tract infection, increased frequency of urination
- cough
- yellowing of the skin and eyes
- high blood levels of bilirubin (a breakdown product of red blood cells)
- **inflammation of a tendon or tendonitis (connective tissues that connect muscles to bones)**

Rare side effects
(may affect up to 1 in 1,000 people)
- rupture of a tendon (connective tissues that connect muscles to bones)

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

You may also have some blood test disorders while taking Eirfem tablets, such as high levels of cholesterol (hypercholesterolemia) or high levels of liver enzymes.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eirfem tablets

Keep out of the sight and reach of children.

Do not use Eirfem tablets after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Further Information

What Eirfem tablets contain:
The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.

The other ingredients are cellulose microcrystalline, silica colloidal anhydrous, sodium starch glycolate (type A) and magnesium stearate. The coating is composed of polyvinyl alcohol, polyethylene glycol, titanium dioxide (E171), talc, yellow iron oxide (E172), sunset yellow FCF (E110).

What Eirfem tablets looks like and contents of the pack
Eirfem tablets are supplied as film-coated tablets. The film-coated tablets are yellow and round, biconvex in shape, with "2.5" imprinted on one side of the tablet and plain on the reverse. Each blister pack contains 10, 14, 28, 30, or 100 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer(s):
The marketing authorisation holder is Rowa Pharmaceuticals Limited, Bantry, Co. Cork, lreland.

Manufacturer(s):
EirGen Pharma Limited, 64/65 Westslde Business Park, Old Kilmeaden Road, Waterford, Ireland
Genepharm S.A., 18th Km. Marathon Ave., 15351 Pallini, Greece.

This medicinal product is authorised in the member states of the EEA under the following names:
Ireland - Eirfem 2.5 mg film-coated tablets

This leaflet was last revised in: September 2019