

Cinfaletro® 2.5 mg film-coated tablets

letrozole

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

1. What Cinfaletro® is and what it is used for

What Cinfaletro® is and how it works

Cinfaletro® 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. Cinfaletro® 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 Cinfaletro® is used for

Cinfaletro® 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. Cinfaletro® 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 Cinfaletro® works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Cinfaletro®

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

Do not take Cinfaletro®

- 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 Cinfaletro®

- 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 Cinfaletro® 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 Cinfaletro®.

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 Cinfaletro®

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 Cinfaletro® 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 Cinfaletro®.
- You must not take Cinfaletro® 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.

Cinfaletro® 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.

Cinfaletro® 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 Cinfaletro®

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 Cinfaletro® to be taken once a day. Taking Cinfaletro® 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 Cinfaletro®

Continue taking Cinfaletro® 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 Cinfaletro®, talk to your doctor.

Follow-up during Cinfaletro® 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.

Cinfaletro® 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 Cinfaletro® than you should

If you have taken too much Cinfaletro®, 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 Cinfaletro®

- 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 Cinfaletro®

Do not stop taking Cinfaletro® unless your doctor tells you to. See also the section above “How long to take Cinfaletro®”.

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 Cinfaletro®:

- 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 Cinfaletro® 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 or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cinfaletro®

- Keep out of the reach and sight of children.
- Do not use Cinfaletro® 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.

6. Contents of the pack and other information

What Cinfaletro® contains

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

The other ingredients of the tablet core are: lactose monohydrate, sodium carboxymethyl starch, microcrystalline cellulose, hypromellose, anhydrous colloidal silica and magnesium stearate. The ingredients of the tablet coating, Opadry Yellow, are: hypromellose, macrogol 6000, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172) and tartrazine (E102).

What Cinfaletro® looks like and contents of the pack

Cinfaletro® is supplied as cylindrical, biconvex, yellow film-coated tablets and engraved code L on one side.

Cinfaletro® is supplied in packages containing 30 tablets (in 10 tablets blister-packs).

Manufacturer:

Dosage Form, Packaging & Labeling

LABORATORIOS CINFA, S.A.
Avda. Roncesvalles s/n, 31699
Olloki (Navarra), Spain

Batch Releaser

LABORATORIOS CINFA, S.A.
Olaz-Chipi, 10 – Polígono Industrial Areta
31620 Huarte (Navarra), Spain

Marketing Authorisation Holder

LABORATORIOS CINFA, S.A.
Olaz-Chipi, 10 – Polígono Industrial Areta
31620 Huarte (Navarra), Spain

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This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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