

FERA

letrozole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FERA.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FERA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What FERA is used for

FERA 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.

FERA belongs to a family of medicines called aromatase inhibitors. They are also called "antioestrogens" because they act by reducing the production of oestrogen in your body.

Oestrogen stimulates the growth of certain types of breast cancer. These cancers are called "oestrogen-dependent." Reducing the production of oestrogen may help to keep the cancer from growing.

This may be the first time you are taking an "antioestrogen" or you may have taken another "antioestrogen" such as tamoxifen in the past.

Your doctor may have prescribed FERA for another reason. Ask your doctor if you have any questions about why FERA has been prescribed for you.

FERA is available only with a doctor's prescription.

Before you take FERA

When you must not take it

Do not take FERA if you are allergic to medicines containing letrozole or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take FERA if you are still having periods.

This medicine is only used in women who are no longer having periods.

Women of child-bearing age who recently became postmenopausal or perimenopausal should use a proven method of birth control to avoid pregnancy, until your postmenopausal status is fully established.

Do not take FERA if you are pregnant or breastfeeding.

FERA may affect your baby if you take it while pregnant or breastfeeding.

Do not take FERA if the expiry date (Exp.) printed on the pack has passed.

Do not take FERA if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have severe kidney or liver disease.

Your doctor may want to take special precautions while you are taking this medicine.

If you have not told your doctor about any of the above, tell them before you start taking FERA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may be affected by FERA, or may affect how well it works.

Your doctor can tell you what to do when taking FERA with other medicines.

How to take FERA

How much to take

The usual dose is one FERA tablet daily.

Follow all directions given to you by your doctor and pharmacist carefully.

How to take FERA

Swallow the tablets with a glass of water or other liquid.

If your stomach is upset after taking the tablets, take it with a meal or after a snack.

If you forget to take FERA

If it is almost time for your next dose (e.e. within 2 to 3 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take FERA for

Your doctor will check your progress to make sure the medicine is working and will decide how long your treatment should continue.

If you are unsure, talk to your doctor.

If you take too much FERA (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much FERA. Do this even if there are no signs of discomfort or poisoning.

While you are taking FERA

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking FERA.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking FERA.

If you become pregnant while taking FERA, tell your doctor immediately.

Follow your doctor's instructions carefully.

If you do not follow your doctor's instructions, your treatment may not help or you may have unwanted side effects.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want you to have blood tests from time to time to check on your progress and detect any unwanted side effects. Your doctor may also decide to monitor your bone health as this medicine may cause thinning or wasting of your bones (osteoporosis).

Things you must not do

Do not use FERA to treat any other conditions unless your doctor tells you to.

Do not give FERA to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving, operating machinery or doing anything that requires alertness until you know how FERA affects you.

FERA may cause dizziness or tiredness in some people. If this occurs, do not drive or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking FERA.

Like all other medicines, FERA may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- swelling of the feet, ankles or other parts of the body due to fluid build up
- skin rash, itching or dry skin
- pain in the muscles, joints or bones; joint stiffness, arthritis
- vaginal spotting or bleeding
- whitish, thick vaginal discharge, vaginal dryness
- headache
- fever
- tiredness, sleepiness, weakness or dizziness
- difficulty sleeping
- numbness or tingling in hands or feet
- mood changes such as anxiety, nervousness, irritability and depression (sad mood)
- forgetfulness
- change in sense of taste
- blurred vision or eye irritation
- stomach upset, nausea (feeling sick) or vomiting, pain in the abdomen
- constipation
- diarrhoea
- dry mouth, sore mouth, mouth ulcers and cold sores
- increased thirst
- breast pain
- hot flushes

- increased sweating
- appetite or weight changes
- hair thinning
- urgent need to urinate (pass water)
- pain or burning sensation when urinating, which may be a sign of an infection
- fast or irregular heartbeat
- thinning of bones (osteoporosis; which can only be identified by laboratory testing), bone fractures.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs that blood clots may have formed, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood
- constant "flu-like" symptoms (chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy) that could be a sign of blood problems.

These side effects can be serious. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using FERA

Storage

Keep FERA where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store FERA or any other medicine in the bathroom or near a sink.

Do not leave FERA in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking FERA, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

FERA is a round yellow tablet.

Each pack contains 30 tablets.

Ingredients

The active ingredient in FERA is letrozole. Each FERA tablet contains 2.5 mg of letrozole.

The tablets also contain:

- lactose
- sodium starch glycollate
- microcrystalline cellulose
- hypromellose
- colloidal anhydrous silica
- magnesium stearate
- Opadry Yellow 03B52094 (ARTG No. 106949).

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Aspen Pharma Pty Ltd
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Australia

Australian registration numbers:
FERA - AUST R 175100