

FEMARA[®]

2.5mg tablets

Letrozole

What is in this leaflet

This leaflet answers some common questions about Femara.

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

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What Femara is used for

Femara 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.

Femara is available in tablets containing 2.5 mg of the active ingredient, letrozole.

Letrozole 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" such as Femara or you may have taken another "antioestrogen" such as tamoxifen in the past.

Ask your doctor if you have any questions about why Femara has been prescribed for you.

Your doctor may have prescribed Femara for another reason.

Femara is only available with a doctor's prescription. It is not addictive.

Before you take Femara

When you must not use it

Do not take Femara if you have an allergy to:

- letrozole, the active ingredient in Femara
- any other ingredients of Femara listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing.

Do not take Femara if you are still having periods.

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

Do not take Femara if you are pregnant or breast feeding.

It may affect your baby if you take it while you are pregnant or breast feeding.

Do not take Femara after the use by (expiry) date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work or it may make you unwell.

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

In that case, return it to your pharmacist.

Before you start to take it

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.

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

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of these things, tell them before you take Femara.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Other medicines may be affected by Femara or they may affect how well it works.

Your doctor or pharmacist can tell you what to do when taking Femara with other medicines.

How to take Femara

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

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is one Femara tablet daily.

How to take it

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

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

How long to take it

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 forget to take it

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 go back to taking your tablet as you would normally.

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor or the Poisons and Hazardous Chemicals National Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to the Accident and Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much Femara. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

While you are taking Femara

Things you must do

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

You should not take this medicine while you are pregnant.

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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Femara.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Femara.

Things you must not do

Do not use Femara to treat any other complaints unless your doctor says you can.

Do not give this medicine to anyone else, even if their symptoms seem to be similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Femara until you know how it affects you.

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, 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 Femara.

It may have unwanted side effects in some people in addition to its beneficial effects. All medicines have side effects. 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 immediately or go to Accident and Emergency at your 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.
- 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.
- Tightness or feeling of heaviness in the chest or pain radiating from your chest to your arms or shoulders, neck, teeth or jaw, abdomen or back (sign of angina pectoris or heart attack)
- Numbness or weakness in arm or leg or any part of the body, loss of coordination vision changes, sudden headache, nausea, difficulty speaking or breathing (sign of stroke).
- 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)

The above side effects may be serious. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects 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 heartbeats
- thinning of bones (osteoporosis), leading to bone fractures in some cases
- high levels of cholesterol in the blood (hypercholesterolemia)
- abnormal liver function test results (blood test disorder)
- disturbed physical sensitivity (dysaesthesia)

Tell your doctor if you notice anything else that is making you unwell.

Other side effects not listed above may happen in some people.

Some of these can only be found by laboratory testing.

After taking Femara

Storage

- Keep your tablets in the container until it is time to take them.
- Store the tablets in a cool dry place at below 25 degrees (room temperature)
- Do not store Femara or any other medicine in the bathroom or any other place that is hot or steamy.
- Do not leave the tablets in the car or on window sills.

Heat and dampness can destroy some medicines. Femara will keep well if it is cool and dry.

Keep this medicine 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.

Disposal

If your doctor tells you to stop taking Femara or the tablets have passed their use by (expiry date), ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Femara 2.5 mg: dark yellow, round, coated tablet, marked CG on one side and FV on the other; supplied in blister packs in a cardboard carton of 30 tablets.

Ingredients

Femara tablets contain 2.5 mg of letrozole as the active ingredient.

The tablets also contain:

- silica colloidal anhydrous
- microcrystalline cellulose
- lactose
- magnesium stearate
- starch-maize
- sodium starch glycollate
- hypromellose
- iron oxide yellow CI 77492

- macrogol 8000
- talc-purified
- titanium dioxide

Femara does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Femara is supplied in New Zealand by:

Novartis New Zealand Limited

Private Bag 65904

Mairangi Bay

Auckland

Building G, 5 Orbit Drive

Rosedale

Auckland 0632

Telephone 0800 652 422

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