

LETROZOLE FBM

contains the active ingredient letrozole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LETROZOLE FBM.

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 LETROZOLE FBM 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 LETROZOLE FBM is used for

LETROZOLE FBM 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.

LETROZOLE FBM belongs to a group of medicines called aromatase inhibitors also called 'antioestrogens'. These medicines work 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 LETROZOLE FBM or you may have taken another "antioestrogen" such as femara or tamoxifen in the past.

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

LETROZOLE FBM is available only with a doctor's prescription.

There is no evidence that LETROZOLE FBM is addictive.

Before you take LETROZOLE FBM

When you must not take it

Do not take LETROZOLE FBM if you are allergic to medicines containing letrozole or aromatase inhibitors (class) medicine 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 LETROZOLE FBM 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 peri menopausal should use a proven method of birth control to avoid pregnancy, until your post menopausal status is fully established.

Do not take LETROZOLE FBM if you are pregnant.

LETROZOLE FBM may affect your developing baby if you take it during pregnancy.

Do not take LETROZOLE FBM if you are breastfeeding.

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

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

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:

- suffer from a disease of the bone that leads to loss of bone protein and minerals (osteoporosis) resulting in an increased risk of fracture and/or you have a history of recurrent fractures
- have not yet gone through menopause

Your level of hormones may be checked by your doctor before you take LETROZOLE FBM to ensure you have gone through the menopause (cessation of periods).

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

Tell your doctor if you plan to become pregnant or breastfeed

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

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 LETROZOLE FBM, or may affect how well it works. This includes in particular:

- tamoxifen
- other anti-estrogens or estrogencontaining therapies

These substances may diminish the action of LETROZOLE FBM.

Women of child-bearing potential

If you still until recently had menstrual periods, you should discuss with your doctor about the necessity of effective contraception as you might have the potential to become pregnant.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking LETROZOLE FBM.

How to take LETROZOLE FBM

How much to take

The usual dose is one LETROZOLE FBM tablet.

Your doctor may advise you to take a different dose. This depends on your condition and whether or not you are taking any other medicines.

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

How to take LETROZOLE FBM

Swallow the tablets with a whole glass of water.

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

If you forget to take LETROZOLE FBM

If it is almost time for your next dose, 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 LETROZOLE FBM 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 take too much LETROZOLE FBM (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 LETROZOLE FBM. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking LETROZOLE FBM

Things you must do

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

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

If you become pregnant while taking LETROZOLE FBM, 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.

Your doctor may want you to have blood tests from time to time to check on your progress and detect 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).

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

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

Things you must not do

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

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

Things to be careful of

Be careful driving or operating machinery until you know how LETROZOLE FBM affects you.

This medicine may cause drowsiness, dizziness or light headedness in some people. If any of these occur, do not drive, operate machinery 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 LETROZOLE FBM.

Like all other medicines, LETROZOLE FBM 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:

- 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
- high level of cholesterol
- 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
- thirst, change in sense of taste, dry mouth
- dry mucous membranes of the mouth, nose, vagina
- 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), bone fractures
- cough
- trigger finger, a condition in which your finger or thumb catches in a bent position

Tell your doctor straight away if you experience any of the following:

- 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)
- blurred vision (sign of cataract)
- swelling of the feet, ankles or other parts of the body due to fluid build-up (signs of oedema).

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 sign of blood problems
- swelling mainly of the face and throat (signs of allergic reaction)
- weakness or paralysis of limbs or face, difficulty speaking (signs of stroke)
- crushing chest pain or sudden arm or leg (foot) pain (signs of a heart attack)
- swelling and redness along a vein which is extremely tender, possibly painful to touch (signs of thrombophlebitis).

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

Other side effects not listed above may also occur in some patients. Some of these can only be found by laboratory testing.

After using LETROZOLE FBM

Storage

Keep LETROZOLE FBM 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 the container until it is time to take them.

If you take the tablets out of the container they may not keep well.

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

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

Do not leave LETROZOLE FBM in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking LETROZOLE FBM, 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

LETROZOLE FBM is a yellow, round biconvex film-coated tablet with 'LET1' on one side and plain on the other side.

Each blister pack contains 30 tablets.

Ingredients

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

The tablets also contain:

- cellulose - microcrystalline
- hypromellose
- lactose
- magnesium stearate
- opadry 03F52007 yellow
- silica - colloidal anhydrous
- sodium starch glycollate
- starch - maize.

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

Supplier

Southern Cross Pharma Pty Ltd
56 Illabunda Drive
Malua Bay NSW 2536
ABN 47 094 447 677

Australian registration numbers:
LETROZOLE FBM - AUST R 167833

Date of preparation: November 2013.