

Letrozole Actavis

contains the active ingredient letrozole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LETROZOLE ACTAVIS.

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 ACTAVIS 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 ACTAVIS is used for

LETROZOLE ACTAVIS 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 ACTAVIS 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 or you may have taken another "antioestrogen" such as tamoxifen in the past.

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

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

There is no evidence that LETROZOLE ACTAVIS is addictive.

Before you take LETROZOLE ACTAVIS

When you must not take it

Do not take LETROZOLE ACTAVIS 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, shortness of breath or troubled breathing.

Do not take LETROZOLE ACTAVIS 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 ACTAVIS if you are pregnant.

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

Do not take LETROZOLE ACTAVIS if you are breastfeeding.

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

Do not take LETROZOLE ACTAVIS 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. Your doctor will want to know if you are prone to allergies.

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 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 ACTAVIS.

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 ACTAVIS, or may affect how well it works.

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

How to take LETROZOLE ACTAVIS

How much to take

The usual dose is one LETROZOLE ACTAVIS tablet.

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

How to take LETROZOLE ACTAVIS

Swallow the tablets with a glass of water.

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

If you forget to take LETROZOLE ACTAVIS

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 ACTAVIS 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 LETROZOLE ACTAVIS (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 ACTAVIS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking LETROZOLE ACTAVIS

Things you must do

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

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

If you become pregnant while taking LETROZOLE ACTAVIS, 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 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 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 ACTAVIS.

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

Things you must not do

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

Do not give LETROZOLE ACTAVIS 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 ACTAVIS affects you.

This medicine may cause drowsiness and dizziness in some people. If 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 ACTAVIS.

Like all other medicines, LETROZOLE ACTAVIS 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
- 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), 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 sign of blood problems.

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

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 ACTAVIS

Storage

Keep LETROZOLE ACTAVIS 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 pack until it is time to take them.

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

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

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

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking LETROZOLE ACTAVIS, 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 ACTAVIS is a round, yellow lenticular film-coated tablet.

Each pack contains 30 and 100 tablets.

Ingredients

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

The tablets also contain:

- lactose
- maize starch
- sodium starch glycollate
- microcrystalline cellulose
- magnesium stearate
- Opadry II 85F32410 Yellow

(ARTG 107176).

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

Supplier

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Australian registration numbers:

LETROZOLE ACTAVIS - AUST R 176276

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