

Letrozole AN tablets

Letrozole tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Letrozole AN.

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 AN 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 AN is used for

Letrozole AN is used for the treatment of breast cancer in post-menopausal women i.e. women who no longer have periods, either because of their natural age or following surgery or chemotherapy

Letrozole belongs to a family of medicines called aromatase inhibitors (also referred to as antioestrogens). They function by decreasing the amount of the hormone oestrogen that is produced in your body.

The growth of certain types of breast cancer is promoted by oestrogen.

These cancers are known as "oestrogen-dependent". Decreasing the production of oestrogen may aid to prevent the cancer from growing.

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

If you have any questions about why Letrozole AN has been prescribed for you, ask your doctor.

You may have been prescribed Letrozole AN by your doctor for another reason.

Letrozole AN is only obtainable with a doctor's prescription.

Letrozole AN is not addictive.

Before You Take Letrozole AN

When you must not take it

Do not take Letrozole AN if you are allergic to:

- Letrozole, the active ingredient in this medicine
- Any of the other ingredients of this medicine listed at the end of this leaflet.

If you get an allergic reaction, symptoms 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 Letrozole AN if you have not yet experienced menopause.

This medicine is intended only to be used in post-menopausal women (ie women who no longer have their periods).

Women of child bearing age who have recently become postmenopausal or perimenopausal are advised to use a

proven method of birth control to avoid pregnancy until postmenopausal status is fully determined.

Do not use Letrozole AN if you are pregnant or breastfeeding as it may affect your baby.

Do not use Letrozole AN after the expiry date printed on the pack.

It may have no effect at all, or worse, have an entirely unexpected effect if you take it after the expiry date.

Do not use Letrozole AN if the packaging is torn or shows signs of tampering.

In such case, please return it to your doctor or pharmacist.

Do not use it to treat any other complaints unless your doctor says it's safe.

Do not give this medicine to anyone else, for disposal

Before you start to take it

You must tell your doctor if you have severe kidney or liver disease.

Your doctor might take special precautions while you are taking this medication.

Tell your doctor if you have a history of osteoporosis or bone fractures.

Your level of hormones may be checked by your doctor before you take letrozole, 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.

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

Females of child-bearing potential and male patients

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. Ask your doctor about options of effective birth control.

Letrozole may reduce fertility in male patients.

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.

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

Your doctor or pharmacist can tell you what to do when taking letrozole with other medicines. This includes in particular:

- tamoxifen
- other anti-estrogens or estrogen containing therapies
- medicines used to treat infections, such as ketoconazole, itraconazole, voriconazole, ritonavir and clarithromycin, rifampicin
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbital
- St. John's Wort (a herbal supplement)

These medicines may increase or diminish the action of Letrozole AN.

How to take Letrozole AN

When taking Letrozole AN, follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to take

The usual dose is one Letrozole AN tablet taken per day.

How to take it

Letrozole AN tablets should be swallowed whole with a glass of water or other liquid.

If you get an upset stomach after taking the tablets, take it with a meal or a snack.

How long to take it

Continue taking Letrozole AN for as long as your doctor or pharmacist tells you.

Your progress will be checked by your doctor to ensure this medicine is working. Your doctor will make a decision on how long your treatment should continue.

Talk to your doctor if you are unsure.

If you forget to take it

If it is almost time for your next dose (eg within 2-3 hours), then 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.

If you take too much (overdose)

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

You may need urgent medical attention.

While you are taking Letrozole AN

Things you must do

Tell your doctor immediately, if you become pregnant while taking Letrozole AN. This medicine should not be taken while you are pregnant.

Your doctor's instructions should be followed carefully.

If you do not, your treatment may not be helpful or you may have unwanted side effects.

Make sure you go to all of your doctor's appointments so that your progress can be checked.

Your doctor may ask you to have blood tests from time to time to check on your progress and pick up any unwanted side effects. Furthermore, your doctor may decide to

assess the health of your bones as this medicine may cause thinning or wasting of your bones (osteoporosis).

Tell your doctor, dentist or pharmacist that you are on Letrozole AN if you are about to start taking any other new medicine.

Tell any other doctor, dentist or pharmacist who treats you that you are using Letrozole AN.

Things you must not do

Do not use Letrozole AN to treat any other complaints unless your doctor says it's safe.

Do not give this medicine to anyone else, even if they have the same symptoms as you.

Things to be careful of

Be careful driving or operating machinery or doing other jobs which require you to be alert until you know how Letrozole AN affects you.

This medicine may cause tiredness, dizziness or lightheadedness 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 AN.

Letrozole helps most people, but it may have unwanted side effects in some people. All medicines have side effects. Sometimes they are serious but most of the time they are not. You may require medical treatment if you get some of the side effects.

Do not be worried by the list of possible side effects. You may not even experience any of them.

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

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

- signs that blood clots could 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 thighs or calves, chest pain, difficulty in breathing, coughing blood.
- continuous "flu-like" symptoms such as chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy, which could be signs 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)

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

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 if you have any of the following side effects and they worry you:

- skin rash, itching or dry skin
- pain in the muscles, joints or bones; joint stiffness, arthritis
- high level of cholesterol
- vaginal spotting or bleeding
- whitish, thick vaginal discharge, vaginal dryness
- headache
- fever
- tiredness, sleepiness, weakness or dizziness, vertigo
- falls
- chest pain (mild)
- 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
- upset stomach, nausea (feeling sick) or vomiting, indigestion, abdomen pain
- constipation
- diarrhoea
- dry mouth, sore mouth, mouth ulcers and cold sores
- increased thirst
- dry mucous membranes of the mouth, nose, vagina
- 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
- pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- fast or irregular heartbeats, palpitations, high blood pressure (hypertension)
- thinning of bones (osteoporosis), leading to bone fractures in some cases
- cough
- trigger finger, a condition in which your finger or thumb catches in a bent position.
- dark coloured urine
- yellowish eyes and/or skin (jaundice)

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

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

After taking Letrozole AN

Storage

Keep your tablets in the blister pack until it is time to take them.

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

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

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

Do not leave in the car or on window sills. Heat and dampness can destroy some medicines.

Keep Letrozole AN 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 Letrozole AN, 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 AN 2.5 mg tablets (AUST R 159227) are yellow, round, biconvex, film coated tablets plain on both sides. They are presented in a PVC/PVDC/Al pack size of 30 tablets.

Ingredients

Active Ingredient:

Letrozole.

Each tablet contains 2.5 mg of Letrozole.

Other Ingredients:

- microcrystalline cellulose
- hypromellose
- lactose monohydrate
- magnesium stearate
- colloidal anhydrous silica
- sodium starch glycollate type A
- maize starch
- OPADRY complete film coating system 03B82927 YELLOW

Name and Address of the Sponsor

Juno Pharmaceuticals Pty Ltd
Level 2, 6 Bond Street,
South Yarra,
VIC – 3141

Date of Preparation

March 2019