

ARX-Letrozole

Letrozole

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

The name of your medicine is ARX-Letrozole. It contains the active ingredient letrozole.

Letrozole is used to treat breast cancer in women who are postmenopausal – that is, women who no longer have periods, either naturally due to their age or after surgery or chemotherapy.

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-

dependant." Reducing the production of oestrogen may help keep the cancer from growing.

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

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

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of letrozole in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing letrozole
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant or planning to become pregnant.

Letrozole may affect your developing baby if you take it during pregnancy. Your doctor will discuss with you the potential risks of taking letrozole during pregnancy. There are reports of abnormalities in babies born to mothers who took letrozole during pregnancy.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

Letrozole may pass into human breast milk and there is a possibility that your baby may be affected.

Do not take letrozole 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 this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney or liver disease
- history of osteoporosis or bone fractures

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

Taking other medicines

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

Some medicines and letrozole may interfere with each other. These include:

- azole antifungals (e.g. itraconazole, itraconazole, or voriconazole)
- some antibiotics and antiviral medicines (e.g. clarithromycin, ritonavir, or rifampicin)
- some medicines used to treat epilepsy or seizures (e.g. phenytoin, carbamazepine, or phenobarbital)
- St. John's wort
- clopidogrel, used to prevent blood clots
- tamoxifen
- other anti-oestrogens or oestrogen-containing therapies

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

Other medicines not listed above may also interact with letrozole.

How to take this medicine

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, ask your doctor or pharmacist for help.

How much to take

The recommended dose of letrozole is one tablet daily.

How to take it

Swallow the tablet whole with a full glass of water.

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

When to take it

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your

pharmacist for some hints to help you remember.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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 of this medicine.

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

You may need urgent medical attention.

While you are taking this medicine

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Females of child-bearing potential

If you have only recently stopped having menstrual periods, you should discuss with your doctor about the necessity of effective contraception as you might still have the potential to become pregnant. Ask your doctor about options of effective birth control.

Male patients

Letrozole may reduce fertility in male patients.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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

Letrozole may cause unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- headache
- fever
- nausea, vomiting, indigestion or abdominal pain
- constipation
- diarrhoea
- fatigue, drowsiness, dizziness or vertigo
- fall

- chest pain
- cough
- mood changes such as depression, anxiety, irritability or drowsiness
- high blood cholesterol
- hair loss or thinning
- osteoporosis or bone fractures
- increased sweating
- hot flushes
- vaginal discharge or bleeding
- anorexia or appetite changes
- weight increase or loss
- needing to urinate more often, pain or burning when urinating (sign of urinary tract infection)
- breast pain
- tumour pain (in metastatic setting only)
- low white cell count
- general swelling
- unpleasant or abnormal sense of touch e.g. pins and needles, numbness, burning sensation
- taste disturbance or thirst
- insomnia or difficult sleeping
- memory impairment or forgetfulness
- eye irritation
- fast or irregular heartbeat, high blood pressure or palpitations
- shortness of breath
- increased liver enzymes
- dry mouth, inflamed sore mouth or cold sores
- mucosal dryness of nose, mouth and vagina
- dry skin, itchiness, hives or rash
- pain in the muscles, joints or bones, joint pain, arthritis or back pain
- pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
- trigger finger, a condition in which your finger or thumb catches in a bent position

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- yellow skin and eyes, nausea, loss of appetite or dark coloured urine (signs of hepatitis)
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling or fever (signs of skin disorder)
- blurred vision (may be a sign of a cataract)
- swelling of the feet, ankles or other parts of the body due to fluid build-up

The above list includes serious side effects that may need medical attention.

If any of the following happen, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- rash, red skin, blistering of the lips, eyes or mouth, skin peeling or fever (signs of skin disorder)
- swelling and redness along a vein which is extremely tender, possibly painful to touch (signs of thrombophlebitis)
- signs that a blood clot 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, rapid heartbeat, bluish skin discoloration or fainting
- 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
- weakness or paralysis of limbs or face or difficulty speaking (signs of stroke)
- crushing chest pain or sudden arm or leg (foot) pain (signs of a heart attack)
- symptoms of an allergic reaction including shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

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

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

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What ARX-Letrozole tablets look like

2.5mg Tablet:

Yellow, circular, biconvex film-coated tablets debossed with LT on one side and 2.5 on the other side.
AUST R 309249.

They are available in blister packs of 10 or 30 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 2.5mg of letrozole as the active ingredient.

It also contains the following:

- colloidal anhydrous silica
- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- sodium starch glycollate
- hypromellose
- OPADRY complete film coating system 03B52094 YELLOW

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

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