

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LETROZOLE**

letrozole tablets, USP

Read this carefully before you start taking **LETROZOLE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LETROZOLE**.

Serious Warnings and Precautions

- LETROZOLE should be used under the supervision of a doctor experienced in the use of anti-cancer drugs.
- LETROZOLE may cause osteoporosis (weakened bones) and / or broken bones.

What is LETROZOLE used for?

LETROZOLE is used to treat breast cancer in women who have gone through menopause (cessation of periods). It is used to treat:

- hormone receptor-positive invasive early breast cancer after surgery, or
- hormone receptor-positive invasive early breast cancer after 5 years of tamoxifen therapy or
- advanced breast cancer as a first treatment, or
- breast cancer that has spread to other sites in the body (metastatic) after:
 - disease progression (means that previous treatments did not work well enough and the cancer got worse); or
 - relapse (means that the cancer comes back after previous treatment), previously treated with anti estrogens.

How does LETROZOLE work?

Estrogen is a normally occurring female sex hormone. It stimulates normal breast tissue and the growth of some types of breast cancer.

LETROZOLE is an aromatase inhibitor. It acts by binding to aromatase, which is a substance needed to make estrogen. As a result, this lowers the levels of estrogen in the body. It also reduces the growth of some types of breast cancer.

What are the ingredients in LETROZOLE?

Medicinal ingredient: Letrozole

Non-medicinal ingredients: cellulose compounds (microcrystalline cellulose and hypromellose), maize starch, iron oxide yellow, lactose monohydrate, magnesium stearate, polyethylene glycol, sodium starch glycolate, colloidal anhydrous silica, talc and titanium dioxide

LETROZOLE comes in the following dosage forms:

Tablets, 2.5 mg

Do not use LETROZOLE if:

- you have ever had an unusual or allergic reaction to letrozole or any other ingredient in LETROZOLE.
- you still have menstrual periods.
- you can still become pregnant, or are pregnant. It may harm you and the baby or make you lose the pregnancy.
- you are breast-feeding.
- you are under 18 years of age.
- you have hormone-receptor negative breast cancer.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LETROZOLE. Talk about any health conditions or problems you may have, including if you:

- have or have had any disorder or disease which affects your liver or kidneys.
- have taken or are taking hormone replacement therapy.
- have taken or are taking other medication to treat your cancer.
- have a personal or family history of osteoporosis or have ever been diagnosed with low bone density or have a recent history of fractures (in order for your doctor to assess your bone health on a regular basis).
- have a personal or family history of high blood cholesterol or lipid levels.
- have or have had cardiovascular or heart disease including any of the following: heart attack, stroke or uncontrolled blood pressure.

Other warnings you should know about:

Pregnancy:

- If you are perimenopausal or have recently entered menopause, you may still be able to get pregnant. If this applies to you, you will need to use effective birth control while you are taking LETROZOLE for at least 20 days after stopping your treatment. Ask your doctor about options for effective birth control.
- If you get pregnant while taking LETROZOLE contact your healthcare professional right away.

Fertility: LETROZOLE may reduce fertility in males. This means it may be harder for you to father a child in the future.

Check-ups and testing: You will have blood tests done during your treatment to check your cholesterol and hormones levels. Your hormone levels may be checked before you start taking LETROZOLE and regularly during the first 6 months of treatment. Your healthcare professional will also monitor your bone health during your treatment.

Driving a vehicle or using machinery: LETROZOLE may make you feel tired, dizzy or sleepy. If this happens, you should not drive or operate any tools or machinery until you feel normal again.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LETROZOLE:

- medicines used to treat bacterial, fungal, yeast or viral infections (including HIV) such as clarithromycin, rifampicin telithromycin, ketoconazole, itraconazole, voriconazole and ritonavir.

- a medicine used to treat lymphoma called methoxsalen
- a medicine used in the treatment of breast cancer called tamoxifen
- a medicine used to prevent blood clots called clopidogrel
- medicines used to treat seizures such as phenytoin, carbamazepine and phenobarbital
- an herbal remedy used to treat depression called St. John's Wort
- other anti-estrogens or therapies that contain estrogen

How to take LETROZOLE:

- Take 1 tablet once per day with or without food, at about the same time each day.
- Swallow tablet whole with a small glass of water.

Usual dose: 1 tablet (2.5 mg) per day

Overdose:

If you think you, or a person you are caring for, have taken too much LETROZOLE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of LETROZOLE, take it as soon as you remember. If it is almost time for your next dose (e.g. within 2 or 3 hours), skip it and continue with your regular dosage schedule. Do not take a two doses at once to make up for the one that you missed.

What are possible side effects from using LETROZOLE?

These are not all the possible side effects you may have when taking LETROZOLE. If you experience any side effects not listed here, tell your healthcare professional.

Some side effects, such as hot flushes, hair loss or vaginal bleeding may be due to the lack of estrogen in your body.

- hot flushes
- increased sweating
- night sweats
- fatigue (including weakness and generally feeling unwell)
- headache
- rash
- dizziness, vertigo
- nausea, vomiting, indigestion, constipation, diarrhea
- increase in or loss of appetite
- leaking urine by accident (urinary incontinence)
- weight increase
- anxiety
- insomnia
- hair loss
- vaginal bleeding
- dry skin
- abdominal pain

- back pain
- fall
- palpitations (rapid heart rate)
- nervous disorders (such as nervousness, irritability, drowsiness)
- pain or burning sensation in the hands or wrists (carpal tunnel syndrome)
- reduced sense of touch
- eye irritation
- vaginal disorders (such as discharge or dryness)
- breast pain
- fever
- thirst, taste disorder, dry mouth
- dryness of mucous membranes
- weight decrease
- cough
- trigger finger, a condition in which your finger or thumb catches in a bent position.

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom/ effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| Very Common | | | |
| Hypercholesterolemia: increased levels of cholesterol | | ✓ | |
| Common | | | |
| Myalgia: muscle pain and Arthralgia: bone and joint pain | ✓ | | |
| Arthritis: joint stiffness | ✓ | | |
| Depression: persistent sad mood | | ✓ | |
| Hyperglycemia: increased blood sugar | | ✓ | |
| Hypertension: increased blood pressure | | ✓ | |
| Osteoporosis (bone loss) and Bone fractures | | ✓ | |
| Uncommon | | | |
| Angina (chest pain when your heart muscle doesn't get enough oxygen) or Myocardial Infarction (heart attack): tightness or feeling of heaviness in the chest, pain radiating from your chest to your arms or shoulders, neck, teeth or jaw, abdomen or back | | | ✓ |
| Stroke (lack of blood to the brain): numbness or weakness in arm or leg or any part of the body, loss of coordination, vision changes, sudden headache, nausea, loss of coordination, difficulty in speaking or breathing | | | ✓ |
| Thrombophlebitis (inflammation of a vein due to a blood clot): swelling and redness along a vein which is extremely tender and possibly painful when touched | | | ✓ |
| Pulmonary embolism (blood clot in the lung): difficulty breathing, chest pain, fainting rapid heart rate, bluish skin discoloration | | | ✓ |

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| Edema: swelling of arms, hands, feet, ankles or other parts of the body | | | ✓ |
| Angioedema: severe swelling of face, lips, tongue and throat | | ✓ | ✓ |
| Allergic reaction: swelling mainly of the face and throat | | | ✓ |
| Anaphylaxis: severe allergic reaction | | ✓ | ✓ |
| Neutropenia (low white blood cells): severe fever, chills or mouth ulcers due to infections | | | ✓ |
| Cataract (clouding of the lens of the eye): blurred vision | | | ✓ |
| Liver problems including hepatitis (inflammation of the liver): yellow skin and eyes (jaundice), nausea, loss of appetite, dark-coloured urine (increased bilirubin level) | | | ✓ |
| Blood test disorders: abnormal liver function tests | | | ✓ |
| Urinary tract infection: increased frequency of urination | | | ✓ |
| Skin disorder: rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever | | | ✓ |
| Tendon disorders including tendonitis (inflammation of the tendon) and tenosynovitis (inflammation of the tissue surrounding the tendon): pain, swelling and tenderness near a joint | | ✓ | |
| Rare | | | |
| Tendon tears: feel a snap or pop when the tear happens, severe pain, swelling | | ✓ | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

REPORTING SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store your tablets in a dry place at room temperature 15°C to 30°C. Avoid places where the temperature may rise above 30°C. Protect from moisture.

Keep out of the reach and sight of children and pets.

Expiry date:

Do not take LETROZOLE after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of the month. Remember to take any unused medication back to your pharmacist.

If you want more information about LETROZOLE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website www.sivem.ca, or by calling 1-855-788-3153.

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Last revised: OCT 12, 2023