



Drugs and Supplements

Letrozole (Oral Route)

Description and Brand Names

US Brand Name

Femara**Descriptions**

Letrozole is used to treat certain types of breast cancer in women who have already stopped menstruating (postmenopausal). It is also used for women who have already had other cancer treatments (eg, tamoxifen).

Female hormones that occur naturally in the body can increase the growth of some breast cancers. Letrozole works by decreasing the amounts of these hormones in the body.

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

This product is available in the following dosage forms:

- Tablet

Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of letrozole in the pediatric population. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of letrozole in the elderly. However, elderly patients are more sensitive to the effects of this medicine than younger adults.

Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Ceritinib
- Cilostazol
- Clarithromycin
- Tegafur

Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Bone problems (eg, osteoporosis) or

- Hypercholesterolemia (high cholesterol or fat in the blood)—Use with caution. May make these conditions worse.
- Cirrhosis or
- Liver disease, severe—Use with caution. The effects may be increased because of slower removal of the medicine from the body.

Proper Use

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered.

You may take this medicine with or without food.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (tablets):
 - For breast cancer:
 - Adults—2.5 milligrams (mg) once a day.
 - Children—Use and dose must be determined by your doctor.

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Precautions

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It is very important that your doctor check your progress at regular visits to make sure that this medicine is working properly. Blood tests may be needed to check for unwanted effects.

Using this medicine while you are pregnant can harm your unborn baby. Use an effective form of birth control to keep from getting pregnant during treatment with this medicine and for at least 3 weeks after your last dose. If you think you have become pregnant while using the medicine, tell your doctor right away.

This medicine may decrease bone mineral density when used for a long time. A low bone mineral density can cause weak bones or osteoporosis. If you have any questions about this, talk to your doctor.

This medicine may increase the amount of cholesterol and fat in the blood. If this happens, your doctor may give you medicine to lower the cholesterol and fat in the blood.

This medicine may make you dizzy, drowsy, or tired than they are normally. Do not drive or do anything else that could be dangerous until you know how this medicine affects you.

Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Less common

- Bone fracture
- breast pain
- chest pain
- chills, fever, or flu-like symptoms
- mental depression
- swelling of the feet or lower legs

Rare

- Continuing or severe nervousness
- cough
- dizziness or lightheadedness
- fainting
- fast heartbeat
- heart attack
- increased sweating
- nausea
- pain in the chest, groin, or legs, especially the calves

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- severe and sudden, unexplained troubled breathing
- severe, sudden headache
- slurred speech
- sudden loss of coordination
- sudden, severe weakness or numbness in the arm or leg
- swollen glands
- vaginal bleeding
- vision changes

Incidence not known

- Black, tarry stools
- blindness
- blurred vision
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- chest discomfort
- dark urine
- decreased vision
- dilated neck veins
- extreme tiredness or weakness
- general tiredness or weakness
- increased need to urinate
- irregular breathing
- irregular heartbeat
- light-colored stools
- painful or difficult urination
- passing urine more often
- sore throat
- sores, ulcers, or white spots on the lips or in the mouth
- unusual bleeding or bruising
- unusual tiredness or weakness
- upper right abdominal pain
- weight gain
- white or brownish vaginal discharge
- yellow eyes and skin

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Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- Back pain
- bone pain
- hot flashes (sudden sweating and feeling of warmth)
- joint pain
- muscle pain

Less common

- Anxiety
- confusion
- constipation
- diarrhea
- dry mouth
- headache
- increased thirst
- loss of appetite or weight loss
- metallic taste
- skin rash or itching
- sleepiness
- spinning or whirling sensation causing loss of balance
- stomach pain or upset
- trouble sleeping
- vomiting
- weakness

Incidence not known

- Bad, unusual, or unpleasant (after) taste and thirst
- being forgetful
- change in taste
- dryness of the skin
- hair loss
- hives or welts

- increased appetite
- irritability
- nervousness
- red, sore eyes
- redness of the skin
- swelling or inflammation of the mouth

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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