

Letrozole Sandoz®

Letrozole film-coated tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Letrozole Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

You should ensure that you speak to your pharmacist or doctor to obtain the most current information on the medicine.

You can also download the current leaflet from www.sandoz.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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 LETROZOLE SANDOZ IS USED FOR

This medicine 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.

The name of the medicine is called Letrozole Sandoz. It contains the active ingredient letrozole.

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-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 Sandoz or you may have taken another "antioestrogen" 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 it for another reason.

This medicine is not addictive.

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

BEFORE YOU TAKE LETROZOLE SANDOZ

When you must not take it

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

- Letrozole, the active ingredient, or to any of the other ingredient(s) listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

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

Do not take this medicine if you are still having periods.

This medicine is only used in women who are no longer having periods.

If you recently become postmenopausal or if you are perimenopausal, you should discuss with your doctor about the necessity of contraception as you might have the potential to become pregnant. Do not take this medicine if you are pregnant or breast feeding.

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

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 severe kidney or liver disease.

Your doctor may want to take special precautions while you are taking this medicine.

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 Sandoz to ensure you have gone through the menopause (cessation of periods).

Tell your doctor if you are allergic to any other medicines, foods, preservatives or dyes.

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of these things, tell him/her before you start taking Letrozole Sandoz.

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.

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

Your doctor or pharmacist can tell you what to do when taking Letrozole Sandoz with other medicines.

This includes in particular:

- tamoxifen
- other anti-estrogens or estrogen-containing therapies.

These substances may diminish the action of Letrozole Sandoz.

Women 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 Sandoz may reduce fertility in male patients.

HOW TO TAKE LETROZOLE SANDOZ

Follow the 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, ask your doctor or pharmacist for help.

How much to take

The usual dose is one Letrozole Sandoz tablet daily.

How to take it

Swallow the tablets with a glass of water or other liquid.

If your stomach is upset after taking your medicine, try taking it with a meal or after a snack.

When to take Letrozole Sandoz

Take your 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.

How long to take Letrozole Sandoz

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 forget to take it

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

Otherwise, take your dose as soon as you remember, and continue to take it as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Letrozole Sandoz. Do this even if there are no signs of discomfort or poisoning. Keep the telephone numbers for these places handy.

You may need urgent medical attention.

WHILE YOU ARE TAKING LETROZOLE SANDOZ

Things you must do

If you become pregnant while taking Letrozole Sandoz, 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 that 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 any 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 Sandoz.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Letrozole Sandoz.

Things you must not do

Do not take Letrozole Sandoz to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Letrozole Sandoz until you know how it affects you.

This medicine may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive 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 Sandoz.

It may have unwanted side effects in some people in addition to its beneficial effects. 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.

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

- 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, rapid heartbeat, bluish skin discolouration, 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
- 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 side effects may be serious. 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 (sign of odema)

Tell your doctor if you notice 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, back pain
- high level of cholesterol
- 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)
- drowsiness
- forgetfulness
- blurred vision or eye irritation
- stomach upset, nausea (feeling sick) or vomiting, indigestion, pain in the abdomen
- constipation
- diarrhoea
- dry mouth, sore mouth, mouth ulcers and cold sores
- thirst, change in sense of taste, dry mouth
- dry mucous membranes of the mouth, nose, vagina
- breast pain
- hot flushes
- increased sweating
- appetite 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 heartbeat, palpitations, high blood pressure (hypertension)
- thinning of bones (osteoporosis), bone fractures
- 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 or pharmacist if you notice anything else that is making you feel unwell.

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

AFTER TAKING LETROZOLE SANDOZ

Storage

Keep your medicine in the original container until it is time to take them.

Store the tablets in a cool dry place where the temperature stays below 30°C (room temperature).

Do not store Letrozole Sandoz or any other medicine in the bathroom or any other place that is hot or steamy.

Do not leave the tablets on a window sill or in the car.

Heat and dampness can destroy some medicines. Letrozole Sandoz will keep well if it is cool and dry.

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.

the other; supplied in blister packs in a cardboard carton of 30 tablets.

Ingredients

Active ingredients:

- Letrozole Sandoz 2.5mg - 2.5mg letrozole.

Inactive ingredients:

- silica - colloidal anhydrous
- microcrystalline cellulose
- lactose monohydrate
- magnesium stearate
- starch-maize
- sodium starch glycollate
- hypromellose
- iron oxide yellow
- macrogol 8000
- purified talc
- titanium dioxide.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
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54 Waterloo Road
Macquarie Park NSW 2113
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Australian Register Number

2.5mg film-coated tablet: AUST R 172124

PRODUCT DESCRIPTION

What it looks like

Letrozole Sandoz 2.5 mg: dark yellow, round, film-coated tablet, marked CG on one side and FV on