LETROMYL
Letrozole Film-coated Tablets 2.5 mg

What is in this leaflet
This leaflet answers some common questions about Letromyl tablets. It does not contain all the information available on this medicine. 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 Letromyl against the benefits they expect it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Letromyl is used for and how it works
Letromyl is used for the treatment of breast cancer in women who are post-menopausal, i.e. women who no longer have periods, either because of their natural age, or following surgery or chemotherapy.

Letromyl contains the active ingredient, letrozole. It belongs to a family of medicines called aromatase inhibitors, also referred to as "anti-oestrogens" as they function by reducing the production of oestrogen in your body.

The growth of certain types of breast cancer is stimulated by oestrogen. These cancers are known as "oestrogen-dependent." Reducing the production of oestrogen may help to prevent the cancer from growing.

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

Your doctor may, however have prescribed Letromyl for another reason. Ask your doctor if you have any questions about why Letromyl has been prescribed for you.

There is no evidence that Letromyl is addictive.

Letromyl is available only with a doctor's prescription.

Before you take Letromyl

When you must not take it
Do not take Letromyl if you are allergic to letrozole, or any of the ingredients listed at the end of this leaflet.
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 Letromyl if you are still having periods.
This medicine is intended only to be used in women who are no longer having periods, i.e. have gone through menopause.

Do not take Letromyl if you are pregnant or breast feeding as it may harm your baby.

Do not take Letromyl 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.

Talk to your doctor or pharmacist if you are not sure whether you should take this medicine.

Before you start to take it
Tell your doctor or pharmacist before taking Letromyl if you have:
- severe kidney disease
- severe liver disease
- a history of osteoporosis or bone fractures.

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

While you should only take Letromyl when you have gone through menopause, your doctor should discuss with you the use of effective contraception. You may still have the potential to become pregnant during treatment with Letromyl.

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

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Letromyl.

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop. Other medicines may be affected by Letromyl or they may affect how well it works.

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

How to take Letromyl

Follow the directions given to you by your doctor and 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 usual dose is one Letromyl tablet taken daily.

**How to take it**
Swallow the tablet with a glass of water or other liquid. Do not crush or chew it. If you get an upset stomach after taking the tablet, take it with a meal or after a snack.

**When to take it**
Take your Letromyl at about the same time each day.

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

**How long to take it for**
Continue taking Letromyl for as long as your doctor or pharmacist tells you to. 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 the dose as soon as you remember, and then go back to taking your medicine as you normally would.

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

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**While you are taking Letromyl**

**Things you must do**
Tell your doctor immediately if you become pregnant while taking Letromyl.

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.

Make sure you go to all of your doctor’s appointments so that your progress can be checked. Your doctor may want you to have tests from time to time to check on your progress and detect any unwanted side effects.

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

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

**Things you must not do**
Do not use Letromyl to treat any other complaints unless your doctor tells you to.

Do not give Letromyl to anyone else, even if their symptoms seem similar to yours.

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

This medicine may cause dizziness or tiredness in some people. If you think 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 Letromyl. All medicines can have some unwanted 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 this list of possible side effects. You may not experience any of them.

Tell your doctor if you notice any of the following side effects and they worry you:

- swelling of the feet, ankles or other parts of the body due to fluid build up
- skin rash, itching or dry skin
- pain in the muscles, joints or bones; joint stiffness, arthritis
- 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)
- forgetfulness
- change in sense of taste
- blurred vision or eye irritation
- stomach upset, nausea (feeling sick) or vomiting, pain in the abdomen
- constipation
- diarrhoea
- dry mouth, sore mouth, mouth ulcers and cold sores
- increased thirst
- appetite or weight changes
- hair thinning
- increased sweating
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- increased swelling
- bone fractures may occur if calcium levels are low (osteoporosis), leading to bone fractures in some cases
- locking of the finger and pain (trigger finger).

Tell your doctor immediately or go to the Emergency department at your nearest hospital if you notice any of the following:
• signs that blood clots may have formed, such as sudden severe headache, sudden loss of co-ordination, 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.
• 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.
• tightness or feeling of heaviness in the chest or pain radiating from your chest to your arms or shoulders, neck, teeth or jaw, abdomen or back (sign of angina pectoris or heart attack)
• numbness or weakness in arm or leg or any part of the body, loss of coordination vision changes, sudden headache, nausea, difficulty speaking or breathing (sign of stroke).
• 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)

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

Tell your doctor if you notice anything else that is making you unwell.
Other side effects not listed above may happen in some people.

Some of these side effects can only be found by laboratory testing.

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

In case of overdose

You must only take the number of tablets that you have been told.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any Letromyl by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

After taking Letromyl

Storage
Keep your Letromyl in the pack until it is time to take them.

Keep your Letromyl in a cool dry place where the temperature stays below 25°C.

Do not store Letromyl or any other medicine in the bathroom or near a sink. Do not leave the tablets in the car or on window sills. Heat and dampness can destroy some medicines.

Keep Letromyl 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
Do not use the medicine after the expiry date printed on the pack.

If your doctor tells you to stop taking this medicine, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like
Letromyl 2.5 mg tablets are dark yellow, capsule shaped, film-coated, slightly biconvex tablets, debossed with “LZ 2.5” on one side and “G” on the other.

The tablets are packed in blister packs containing 60 tablets.

Ingredients
Each Letromyl tablet contains 2.5 mg of the active ingredient letrozole.

The tablets also contain lactose monohydrate, microcrystalline cellulose, maize starch, sodium starch glycinate, magnesium stearate and colloidal silicon dioxide. The film coating contains hypromellose, polydextrose, triacetin, macrogol, iron oxide yellow (E172), quinoline yellow aluminium lake (E104), iron oxide red (E172) and titanium dioxide.

Letromyl does not contain sucrose, gluten or tartrazine.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine
Distributed in New Zealand by:
Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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