

GYNOTRIL™

Letrozole 2.5 mg film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Gynotril. It does not contain all the information that is known about Gynotril.

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 taking Gynotril 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 Gynotril is used for

Gynotril 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.

Gynotril contains 2.5 mg of the active ingredient, letrozole and is presented in tablets.

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 these types of cancers from growing.

This might be the first time you are taking an antioestrogen such as Gynotril or you may have taken another antioestrogen such as tamoxifen in the past.

You must follow all the directions given to you by your doctor. They can differ from the information in this leaflet.

Your doctor can prescribe this medicine for another use.

Always ask your doctor if you need more information.

Gynotril is not known to be addictive.

Gynotril is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take Gynotril if you are allergic to:

- letrozole, the active ingredient in this medicine; or
- any of the other ingredients of Gynotril, as mentioned at the end of this leaflet.

If you get an allergic reaction, symptoms may include:

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

Do not take Gynotril if you are still having periods.

This medicine is intended only to be used in post-menopausal women (i.e. women who no longer have periods).

Women of child-bearing age who have recently become postmenopausal or perimenopausal are advised to use a proven method of birth control to avoid pregnancy until your postmenopausal status is fully determined.

Do not take Gynotril if you are pregnant or breastfeeding as it may affect your baby.

Do not take Gynotril after the use by (expiry) date printed on the pack has passed.

It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take Gynotril if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor says it is safe.

Do not give this medicine to anyone else.

Before you start to take it

If you have severe kidney or liver disease, you must tell your doctor.

Your doctor might take special precautions while you are taking this medication.

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

If you are allergic to any other medicines, foods, dyes or preservatives, you must tell your doctor.

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

If you have not told your doctor any of the above things, please tell them before you begin taking Gynotril.

Taking other medicines

If you are on any other medicine, including medicine from a chemist, supermarket or health shop that you bought without a prescription, you must tell your doctor.

These medicines may affect the way Gynotril works.

Your doctor or pharmacist can tell you what to do if you are taking Gynotril with any other medicine. This includes in particular:

- tamoxifen; or
- other anti-oestrogens or oestrogen containing therapies.

These substances may diminish the action of Gynotril.

Women of child-bearing potential

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.

How to take it

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, you must ask your doctor or pharmacist for help.

How much to take

The usual dose is one Gynotril tablet taken per day.

How and when to take it

GYNOTRIL tablets should be swallowed whole with a glass of water or other liquid.

If you get an upset stomach after the taking the tablet, take it with a meal or after a snack.

How long to take it

Continue taking Gynotril for as long as your doctor or pharmacist tells you.

Your progress will be checked by your doctor to ensure this medicine is working. Your doctor will also make a decision on how long your treatment should continue.

Talk to your doctor if you are unsure.

If you forget to take it

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

Otherwise, take the dose as soon as you remember, then go back to taking your Gynotril tablets as you would normally.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone in Australia 13 11 26) or go to the Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Gynotril. Do this even if there are no signs of discomfort or poisoning.

While you are taking it

Things you must do

Tell your doctor immediately, if you become pregnant while taking Gynotril.

This medicine should not be taken while you are pregnant.

Follow your doctor's instructions carefully.

If you do not, your treatment may not be helpful or you may have unwanted side effects.

Be sure to keep all your appointments with your doctor so your progress can be checked.

Your doctor may ask you to have blood tests from time to time to check on your progress and pick up any unwanted side effects.

Furthermore, your doctor may decide to assess the health of your bones as this medicine may cause thinning or wasting of your bones (osteoporosis).

Tell any other doctors, dentists or pharmacists who are treating you that you are taking Gynotril.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Gynotril.

If you go into hospital, please let the medical staff know you are taking Gynotril.

Things you must not do

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

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

Do not stop taking Gynotril, or lower the dosage, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Gynotril affects you.

This medicine might cause dizziness or tiredness in some people. If you think that you have any of these symptoms, please 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 Gynotril.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be worried by the list of possible side effects. You may not even experience any of them.

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have any of the following:

- signs that blood clots could 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 thighs or calves, chest pain, difficulty in breathing, coughing blood, rapid heartbeat, bluish skin discolouration, fainting;
- constant "flu-like" symptoms such as chills, fever, sore throat, sores in mouth, swollen glands, tiredness or lack of energy, which could be signs 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); and
- swelling and redness along a vein which is extremely tender,

possibly painful to touch (signs of thrombophlebitis).

The above are all serious side effects. 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); or
- swelling of the feet, ankles or other parts of the body due to fluid build-up (signs of oedema).

Tell your doctor if you have 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;
- 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;
- change in sense of taste;
- blurred vision or eye irritation;
- upset stomach, nausea (feeling sick) or vomiting, indigestion, abdomen pain;
- constipation;
- diarrhoea;
- dry mouth, sore mouth, mouth ulcers and cold sores;

- increased thirst, change in sense of taste, dry mouth;
- dry mucous membranes of the mouth, nose, vagina;
- breast pain;
- hot flushes;
- increased sweating;
- appetite changes;
- increase or decrease in weight
- 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; or
- trigger finger, a condition in which your finger or thumb catches in a bent position.

Tell your doctor if you have anything else that is making you unwell. Some people may get other effects while taking Gynotril.

Some of these can be found only through laboratory testing.

After taking it

Storage

Keep your Gynotril tablets in the blister foil until it is time to take them.

If you take Gynotril out of the blister foil, it will not keep well.

Keep it in a cool dry place where the temperature stays below 30°C. Protect from moisture.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep your medicine 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

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

South Melbourne VIC 3205,
Australia

<http://www.eris-pharma.com.au>

Toll free telephone (Australia):
1800 233 588

This leaflet was prepared in May
2016

Gynotril™ 2.5 mg blister pack
AUST R 203379

Version 3

Product description

What GYNOTRIL looks like

Gynotril 2.5 mg tablets are yellow to dark yellow, round, film-coated, biconvex tablets, engraved with 'L' on one face and plain on the other.

Ingredients

Active ingredient: letrozole.

Inactive ingredients:

- colloidal anhydrous silica;
- microcrystalline cellulose;
- lactose monohydrate;
- magnesium stearate;
- maize starch;
- sodium starch glycollate;
- hypromellose;
- macrogol 400;
- titanium dioxide; and
- iron oxide yellow.

Sponsor/Marketing Authorisation Holder



Eris Pharmaceuticals (Australia) Pty
Ltd
6 Eastern Road,