

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Etruzil 2.5 mg, film-coated tablets

letrozole

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms are the same as yours.

Do you experience a lot of discomfort from one of the side effects listed in section 4?

Or do you experience a side effect not listed in this leaflet? Please contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Etruzil and what is it used for?
2. When should you not take Etruzil or be extra careful with it?
3. How to use Etruzil?
4. Possible side effects
5. How to store Etruzil?
6. Contents of the pack and other information

### 1. What is Etruzil and what is it used for?

What is Etruzil and how does it work.

Etruzil contains an active substance called letrozole. It belongs to a group of medicines known as aromatase inhibitors. It is a hormonal (or "endocrine") treatment for breast cancer. The growth of breast cancer is often stimulated by estrogens, which are female sex hormones. Letrozole reduces the amount of estrogen by blocking an enzyme ("aromatase") involved in the production of estrogens. Therefore, it can block the growth of breast cancer that needs estrogen to grow. As a result, the growth of tumor cells and/or the spread to other parts of the body is slowed or stopped.

What is Etruzil and what is it used for.

Etruzil is used to treat breast cancer in women after menopause, that is, after the last menstrual period.

It is used to prevent the recurrence of breast cancer. It can be used as the first treatment when immediate surgery is not suitable, or as the first treatment after breast surgery or following 5 years of treatment with tamoxifen. Etruzil is also used to prevent the spread of breast cancer to other parts of the body in patients with advanced breast cancer.

If you have questions about how Etruzil works or why this medicine has been prescribed for you, contact your doctor.

### 2. When should you not take Etruzil or be extra careful with it?

Follow all instructions from your doctor carefully. The instructions may differ from the general information in this leaflet.

When should you not use this medicine?

- you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- if you are still menstruating, that is, if you have not yet gone through menopause.
- if you are pregnant.
- if you are breastfeeding.

If any of these apply to you, do not take this medicine, and talk to your doctor.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- if you have a severe kidney condition.
- if you have a severe liver condition.
- if you have a history of bone thinning (osteoporosis) or bone fractures (see also Monitoring during the use of Etruzil, in section 3).

If one or more of these apply to you, inform your doctor. Your doctor will take this into account during your treatment with Etruzil.

Letrozole can cause tendon inflammation or tendon injury (see section 4). Rest the painful area if you experience pain in a tendon or swelling of a tendon and contact your doctor.

Children and adolescents up to 18 years

This medicine should not be used by children or adolescents.

Elderly (65 years and older)

This medicine can be used by people aged 65 and older, in the same dosage as for other adults.

Are you taking any other medicines?

Are you taking any other medicines besides Etruzil, or have you recently taken any, or is there a possibility that you will take other medicines in the near future? Then tell your doctor or pharmacist.

Pregnancy, breastfeeding, and fertility

You may only use Etruzil if you have already gone through menopause. However, your doctor should discuss the use of effective contraception with you, as you can still become pregnant during treatment with Etruzil.

You should not use Etruzil if you are pregnant or breastfeeding, as it may be harmful to your baby.

Driving and using machines

If you feel dizzy, tired, sleepy, or generally unwell, do not drive vehicles or use tools or machines until you feel normal again.

Etruzil contains lactose

Etruzil contains lactose (milk sugar). If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Etruzil contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

### 3. How to take Etruzil?

Always take this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist. The recommended dose is one tablet, to be taken once a day. By taking Etruzil at the same time every day, you can more easily remember when to take the tablet.

The tablet can be taken with or without food and should be swallowed whole with a glass of water or another liquid.

How long should Etruzil be used

Continue taking Etruzil every day as long as your doctor has told you to. You may need to use it for months or even years. If you have questions about how long you should continue using Etruzil, ask your doctor.

Monitoring during treatment with Etruzil

Use this medicine only under strict medical supervision. Your doctor will regularly check your condition to see if the treatment is having the desired effect.

Etruzil can cause thinning or wear of your bones (osteoporosis) due to the decrease in estrogens in your body. Your doctor may measure your bone density before, during, and after treatment (a way to check for osteoporosis).

Have you taken too much of this medicine?

If you have taken too much Etruzil, or if someone else accidentally took your tablets, contact your doctor or hospital immediately for advice. Show them the packaging. Medical treatment may be necessary.

Have you forgotten to take this medicine?

If it is almost time for your next dose (e.g., in 2 or 3 hours), skip the missed dose and take the next tablet at the usual time you should take it. In other cases, take the dose as soon as you remember, and then the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Do not stop using Etruzil unless your doctor tells you to. See also the section above "How long should Etruzil be used".

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Most side effects are mild to moderate in nature and will usually disappear after a few days to a few weeks of treatment.

Some side effects, such as hot flashes, hair loss, or vaginal bleeding, may be due to a lack of estrogens in your body.

Do not be alarmed by the list of possible side effects. You may not experience any of these side effects.

Some side effects can be serious:

Sometimes (may occur in up to 1 in 100 people) or rarely (may occur in up to 1 in 1000 people) occurring side effects

Weakness, paralysis, or loss of feeling in an arm or leg or another part of the body, loss of coordination, nausea, or difficulty speaking or breathing (signs of a brain disorder, such as a stroke).

Sudden tight chest pain (sign of a heart disorder).

Difficulty breathing, chest pain, fainting, rapid heartbeat, bluish discoloration of the skin, or sudden pain in arm, leg, or foot (signs that a blood clot may have formed).

Swelling or redness along a vein, which is particularly sensitive and possibly painful to touch. High fever, chills, or mouth ulcers due to infections (lack of white blood cells).

Severe, persistent blurred vision.

If you experience any of the above side effects, inform your doctor immediately. You should also inform your doctor immediately if you experience any of the following side effects during your treatment with Etruzil:

Swelling mainly of the face and throat (signs of an allergic reaction)

Yellow skin and eyes, nausea, loss of appetite, dark-colored urine (signs of hepatitis)

Skin rash, red skin, blisters on the lips, eyes or mouth, peeling skin, fever (signs of a skin condition)

Some side effects are very common (may occur in more than 1 in 10 people).

Hot flashes

Increased cholesterol levels (hypercholesterolemia)

Fatigue

Increased sweating

Pain in bones and joints (arthralgia)

If any of these side effects become severe, consult your doctor.

Some side effects are common (may occur in up to 1 in 10 people).

Skin rash

Headache

Dizziness

Generally feeling unwell (malaise)

Gastrointestinal disorders such as nausea, vomiting, digestive problems, constipation, diarrhea

Increase or loss of appetite

Muscle pain

Bone thinning or wear (osteoporosis), in some cases leading to bone fractures (see also section 3, "Monitoring during treatment with Etruzil")

Swelling of arms, hands, feet, ankles (peripheral edema)

Depressed mood (depression)

Weight gain

Hair loss

Increased blood pressure (hypertension)

Abdominal pain

Dry skin  
Vaginal bleeding  
Palpitations, rapid heartbeat  
Joint stiffness (arthritis)  
Chest pain

If any of these side effects become severe, consult your doctor.

Other side effects occur occasionally (may occur in up to 1 in 100 people).

Nervous system disorders such as anxiety, nervousness, irritability, drowsiness, sleepiness, insomnia, memory problems  
Pain or burning sensation in the hands or wrist (carpal tunnel syndrome)  
Reduction in sensation (especially touch sensation)  
Eye disorders such as eye irritation, blurred vision  
Skin conditions such as itching, dry skin, rash (urticaria)  
Vaginal discharge or dryness  
Breast pain  
Fever  
Thirst, taste disorders, dry mouth  
Dryness of the oral mucosa  
Weight loss  
Urinary tract infection, frequent urination  
Coughing  
Increased enzymes  
Yellow discoloration of the skin and eyes  
High blood concentration of bilirubin (a breakdown product of red blood cells)  
Tendonitis (inflammation of connective tissues that connect muscles and bones)

Some side effects are rare

Tendon rupture (tearing of connective tissues that connect muscles and bones)

Side effects with unknown frequency (cannot be determined from the available data) Trigger finger, a condition where the finger or thumb remains in a bent position..

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, Website: [www.lareb.nl](http://www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

## 5. How to store Etruzil

There are no special storage conditions for this medicine. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and box after EXP. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

## 6. Contents of the packaging and other information.

### What substances are in this medicine?

The active substance in this medicine is letrozole. One film-coated tablet contains 2.5 mg letrozole.

The other substances in this medicine are lactose monohydrate, microcrystalline cellulose (E460), pregelatinized maize starch, sodium starch glycolate, magnesium stearate (E572), colloidal silicon dioxide (E551).

The components of the tablet coating are macrogol, talc (E553b), hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172).

### What does Etruzil look like and what is in a package

Etruzil is a yellow film-coated round tablet, with the inscription L900 on one side and 2.5 on the other side.

Etruzil is available in blister packs of 10, 28, 30, 50, 56, 60, 84, 90, 98, or 100 tablets per box.

Marketing authorization holder:

Egis Pharmaceuticals PLC 1106 Budapest Kereszturi ut 30-38.

Hungary

Manufacturer:

Synthon BV

Microweg 22

6545 CM Nijmegen

Netherlands

Synthon Hispania SL.

C/Castelló,1,

Poligono Las Salinas

08330 Sant Boi de Llobregat

Barcelona

Spain

Rottendorf Pharma GmbH

Ostenfelder strasse 51-61

59320 Ennigerloh

Germany

This medicine is registered in the EEA member states under the following names:

Bulgaria Etruzil 2.5 mg филмирани таблетки

Czech Republic Etruzil 2.5 mg, potahované tablety

Hungary Etruzil filmtabletta

Poland Etruzil

Romania Etruzil 2.5 mg film-coated tablets

Slovakia Etruzil

Netherlands Etruzil 2.5 mg, film-coated tablets

This leaflet was last approved in March 2021.