PACKAGE LEAFLET

Letroks 2.5 mg film-coated tablets
Taken orally.

- ***Active ingredient:*** Each film-coated tablet contains 2.5 mg letrozole.

- ***Excipients:*** contains microcrystalline cellulose, lactose monohydrate (obtained from cow's milk), corn starch, sodium starch glycolate, magnesium stearate, polyvinyl alcohol, titanium dioxide (E171), talc, lecithin, xanthan gum.

Read all of this 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.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- While you are taking this medicine, if you go to a doctor or hospital, please inform your doctor that you are taking this medicine.
- Follow the instructions exactly. Do not use high or low doses other than the recommended dose for you.

What is in this leaflet

1. What Letroks is and what it is used for

Letroks 2.5 mg film-coated tablets, are in the form of tablets coated with film layer. Each tablet contains 2.5 mg letrozole. Letroks is presented in blister packages containing 30 film-coated tablets.

Letroks belongs to a group of medicines called aromatase inhibitors. It is a hormonal (or "endocrine") breast cancer treatment with Letroks.

Growth of breast cancer is frequently stimulated by oestrogens which are female sex hormones. Letroks reduces the amount of oestrogen by blocking an enzyme ("aromatase") involved in the production of oestrogens and therefore may block the growth of breast cancer that needs oestrogens to grow.

As a consequence tumour cells slow or stop growing and/or spreading to other parts of the body. In addition, Letroks can be used to reduce tumour size before breast surgery and also is used to prevent cancer from happening again after breast surgery.

LETROKS is used for the treatment of breast cancer in menopausal women. It is used to prevent the recurrence of cancer. It can be used as the first treatment after breast cancer surgery or after five years of treatment with tamixofen. LETROKS is also used to prevent the spread of breast tumor to other parts of the body in patients with advanced breast cancer.

Follow-up during Letroks treatment
Letroks should only be taken under strict medical supervision.

Your doctor will regularly monitor your condition to check whether the treatment is having the right effect.

Your doctor may also decide to monitor your bone health, because this medicine can cause thinning or damage to the bones (osteoporosis, bone resorption).

If you have any questions about how Letroks is effective or why this medicine is prescribed to you, ask your doctor.

2. What you need to know before you take Letroks

Do not take Letroks in the following conditions:
- if you are allergic to letrozole or any of the other ingredients of Letroks (consult with your doctor if you think you may be allergic),
- if you still have periods (if you have not yet gone through the menopause),
- if you are pregnant,
- if you are breast-feeding.

Take Letroks carefully in the following conditions:
- if you have a severe kidney disease,
- if you have a severe liver disease,
- If you have a history of osteoporosis or bone fractures.

Your doctor may want to check your hormone levels before taking LETROKS to make sure you have menopause.

If any of these conditions apply to you even at any time in the past, please consult to your doctor.

Letroks with food and drink
Letroks can be taken with or without food.

Pregnancy
Consult to your doctor or pharmacist before taking the medicine.

You must not take Letroks if you are pregnant as it may harm your baby. Since Letroks is only
recommended for women in the postmenopausal period, pregnancy-related restrictions will most likely
not apply to you. Nevertheless, if you have recently gone through the postmenopausal period or are

in the premenopausal period, you should talk to your doctor about the need to use contraception, as you may have the potential to become pregnant.

If your menses have continued until recently, you should discuss your need for contraception as you may have the potential to become pregnant.

If you realize that you are pregnant during treatment, immediately consult to your doctor or pharmacist.

Breast-feeding
Consult to your doctor or pharmacist before taking this medicine.
Do not breast-feed your baby if you are taking Letroks. If you are breastfeeding tell your doctor about
it.

Driving and using machines
If you feel dizzy or drowsy or experience vision disturbances with taking Letroks, do not drive or use
machine until you feel normal again.

Important information about some excipients in the formulation of Letroks
Letroks film-coated tablets contain a substance called milk sugar (lactose). If you have been told by
your doctor that you have an intolerance to some sugars, contact your doctor before taking this
medicine.

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially
'sodium-free'.

Other medicines and Letroks
Please inform your doctor or pharmacist if you are currently taking the following drugs or have recently used them.
• Tamoxifen.
• Other anti-estrogens or estrogen-containing treatments
These substances may reduce the effect of LETROKS.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

3. How to take Letroks

Instructions for proper use and dose/frequency of administration:
- The usual dose is one tablet of Letroks to be taken once a day.
- Taking Letroks at the same time each day will help you remember when to take your tablet.
- Always take Letroks exactly as your doctor has told you. Check with your doctor and pharmacist if you are not sure.
- Continue taking Letroks every day for as long as your doctor tells you. You may need to take it for months or even years.

- If you have any questions about how long to keep taking Letroks, talk to your doctor.

Route and method of administration:
- Letroks is for oral administration only.
- You can take Letroks on an empty or full stomach.
- Swallow the tablets preferably with a glass of water at the same time every day.
- Do not chew, divide or crush the tablet.

Different age groups:
Use in children:
Letroks is not used in children or adolescents (under 18 years).

Use in older people:
There is no specific dose recommendation for patients aged 65 years and over.

Special cases for use:
Renal/Hepatic impairment:
No dose adjustment is required for patients with mild hepatic or renal insufficiency. Nevertheless,
patients with severe hepatic impairment require close supervision.

Unless your doctor recommends otherwise, follow these instructions.

Do not forget to take your medicine on time.

Your doctor will tell you how long your treatment will take with Letroks. Do not stop the treatment early because you cannot get the desired effect. You must be under strict medical supervision throughout treatment.

Talk to your doctor or pharmacist if you have an impression that the effect of Letroks is too strong or too weak.

If you take more Letroks than you should
If you take more Letroks than you should, talk to a doctor or pharmacist.
You may need a medical treatment. Take the medicine pack with you and show it to your doctor.

If you forget to take Letroks
If you forget to take your medicine, take the dose as soon as your remember, and then take the next dose at the usual time.

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.

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

If you stop taking Letroks
Stopping Letroks treatment may cause your illness to worsen.
Do not stop taking Letroks unless your doctor tells you to. If you have any further questions on the use of Letroks, consult to your doctor or pharmacist.

4. Possible side effects

Like all medicines, Letroks can cause side effects in people who are sensitive to any of the other
ingredients of this medicine.

Most side effects are mild to moderate and usually resolve a few days to a few weeks after starting treatment.

Some side effects, such as hot flashes, hair loss, or bleeding in the vagina, may be due to the lack of estrogen in your body.

Very common: It can be seen in at least 1 of 10 patients.
Common: Less than one in 10 patients, but more than one in 100 patients.
Uncommon: Less than one in 100 patients, but more than one in 1000 patients.
Rare: Less than one in 1,000 patients, but more than one in 10,000 patients
visible.
Very rare: less than one in 10,000 patients.
Unknown: Unable to predict based on available data.

Don't be intimidated by the following side effects. You may not see any of them.

If any of the below occurs, stop taking Letroks and tell your doctor STRAIGHT AWAY or contact the emergency department of the hospital nearest you:
- Weakness or stroke (paralysis) in arm or leg (extremities) or face, difficulty speaking (sign of a stroke),
- Oppressive chest pain or sudden arm or leg (foot) pain (sign of a heart disorder such as heart attack),
- Swelling and redness along a vein which is extremely tender and possibly painful when touched (sign of blood clot formation (thrombophlebitis) due to inflammation of veins),
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration (sign of a blood clot formation such as obstruction of the lungs with a blood clot (pulmonary embolism)),
- Swelling of the arms, hands, feet, wrists or other parts of the body (signs of oedema),
- Swelling mainly of the face and throat (signs of allergic reaction),
- Severe fever, chills or mouth ulcers due to infections (lack of white blood cells),
- Blurred vision (signs of cataract),
- 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).

These side effects are rare or uncommon.

All of these are very serious side effects.

Tell your doctor if you notice any of the following:

Very common side effects

• Elevated cholesterol levels (hypercholesterolemia)
• Hot flashes
• Increase in sweating
• Fatigue, weakness and restlessness (usually feeling bad)

• Pain in the bones and joints (arthralgia)

Common side effects

• Headache
• rash
• Dizziness
• Gastrointestinal diseases such as nausea, vomiting, indigestion, constipation, diarrhea
• Increase or loss of appetite
• Muscle pain
• Bone thinning or damage (osteoporosis) causing bone fractures in some cases
• Depression
• Weight increase
• Hair loss
• Vaginal bleeding
• Dry skin
• Increase in blood pressure (hypertension)
• Abdominal pain

Uncommon side effects

• Anxiety, anxiety, irritability, hypersensitivity to stimuli
nervous system disorders such as irritability, dizziness, memory problems, insomnia
• Pain or burning sensation in the hands or wrist (carpal tunnel syndrome)
• Impaired sensation, in particular.
• Eye irritation such as eye irritation and blurred vision
• Palpitations, fast heartbeat
• Itchy rash (urticaria)
• Vagina diseases such as discharge or dryness
• Joint stiffness (arthritis)
• Breast pain
• Fire
• Thirst, taste disorder, dry mouth
• Dryness of mucous membranes
• Weight loss
• Urinary tract infection, frequent urination
• Cough
• Abnormal liver function test results (blood test disorders)

Unknown side effects
• Trigger finger (a medical device where your finger or thumb remains in the bent position.
status).

If you experience any side effects not listed in this leaflet, inform your doctor or pharmacist.

Reporting of side effects
Talk to your doctor, pharmacist or nurse in the event of getting any side effects that may or may not

listed in this leaflet. You can also report side effects to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the "Drug Side Effect Notification" icon which is located in www.titck.gov.tr site or calling 0 800 314 00 08 numbered side effect reporting line. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Letroks

Keep Letroks out of the sight and reach of children and in its package.

Store Letroks at room temperature under 25°C. Protect from moisture.

Take this medicine as per the expiry date.

Do not use Letroks after the expiry date which is stated on the carton or blister.

Do not use Letroks if you notice any defects in the product and/or packaging.

Do not throw away any expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder:
BİEM İlaç San. ve Tic. A.Ş.
Turgut Reis Cad. No:21 (06570)
Tandoğan-Çankaya/ANKARA

Manufacturer:
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Gemze Organize Sanayi Bölgesi,
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