

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LETROZOLE 2,5 mg TABLETS PHARMA-Q Film-coated tablets

Letrozole 2,5 mg

Contains sugar (lactose monohydrate 85,00 mg per tablet)

Read all of this leaflet carefully before you start taking LETROZOLE 2,5 mg TABLETS PHARMA-Q

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LETROZOLE 2,5 mg TABLETS PHARMA-Q has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LETROZOLE 2,5 mg TABLETS PHARMA-Q is and what it is used for
2. What you need to know before you take LETROZOLE 2,5 mg TABLETS PHARMA-Q
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1. What LETROZOLE 2,5 mg TABLETS PHARMA-Q is and what it is used for

LETROZOLE 2,5 mg TABLETS PHARMA-Q contains an active substance called letrozole. It belongs to a group of medicines called aromatase inhibitors.

It is a hormonal (or endocrine) breast cancer treatment. Growth of breast cancer is frequently stimulated by oestrogens which are female sex hormones. LETROZOLE 2,5 mg TABLETS PHARMA-Q 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.

LETROZOLE 2,5 mg TABLETS PHARMA-Q is used to treat breast cancer in women who have gone through menopause i.e. cessation of periods. It is used to prevent cancer from happening again. LETROZOLE 2,5 mg TABLETS PHARMA-Q is also used to prevent breast tumour spreading to other parts of the body in patients with advanced breast cancer.

2. What you need to know before you take LETROZOLE 2,5 mg TABLETS PHARMA-Q

Do not take LETROZOLE 2,5 mg TABLETS PHARMA-Q:

- If you are hypersensitive (allergic) to letrozole or any of the other ingredients of LETROZOLE 2,5 mg TABLETS PHARMA-Q (listed in section 6).
- If you still have periods, i.e. if you have not yet gone through the menopause.
- If you have severe kidney disease.
- If you have severe liver disease.
- If you are pregnant.
- If you are breastfeeding.

Warnings and precautions

Take special care with LETROZOLE 2,5 mg TABLETS PHARMA-Q:

- If you have a history of osteoporosis or bone fractures
- If you are taking tamoxifen or other oestrogen containing or oestrogen blocking medicines.
- If you have any signs of tendon pain or swelling – rest the painful area and contact your doctor. LETROZOLE 2,5 mg TABLETS PHARMA-Q may cause inflammation in tendons or tendon injury.

If any of these conditions apply to you, tell your doctor. Your doctor will take this into account during your treatment with LETROZOLE 2,5 mg TABLETS PHARMA-Q.

LETROZOLE 2,5 mg TABLETS PHARMA-Q may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body. Your doctor may decide to measure your bone density (a way of monitoring for osteoporosis) before, during and after treatment.

Children and adolescents (below 18 years)

Children and adolescents should not take LETROZOLE 2,5 mg TABLETS PHARMA-Q.

Other medicines and LETROZOLE 2,5 mg TABLETS PHARMA-Q

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Especially tell your doctor if you are also taking medicines containing any of the following:

- tamoxifen and other anti-oestrogens (used for breast cancer) may reduce the effect of LETROZOLE 2,5 mg TABLETS PHARMA-Q
- oestrogens (used to reduce symptoms of menopause) may reduce the effect of LETROZOLE 2,5 mg TABLETS PHARMA-Q
- phenytoin (used for epilepsy), LETROZOLE 2,5 mg TABLETS PHARMA-Q may prolong the

effect if given together

- clopidogrel (used to prevent blood platelets from clotting), LETROZOLE 2,5 mg TABLETS PHARMA-Q may prolong the effect if given together

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LETROZOLE 2,5 mg TABLETS PHARMA-Q.

You should only take LETROZOLE 2,5 mg TABLETS PHARMA-Q when you have gone through the menopause (cessation of periods). However, your doctor should discuss with you the use of effective contraception, as you may still have the potential to become pregnant during treatment with LETROZOLE 2,5 mg TABLETS PHARMA-Q. You must not take LETROZOLE 2,5 mg TABLETS PHARMA-Q if you are pregnant or breastfeeding as it may harm your baby.

Driving and using machines

LETROZOLE 2,5 mg TABLETS PHARMA-Q may make you feel dizzy, tired, wanting to sleep and drowsy therefore affecting your ability to drive and use machines. You should not drive or use machines before you know how treatment with LETROZOLE 2,5 mg TABLETS PHARMA-Q affects you.

LETROZOLE 2,5 mg TABLETS PHARMA-Q contains lactose

LETROZOLE 2,5 mg TABLETS PHARMA-Q contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, like galactose or lactose, contact your doctor before taking LETROZOLE 2,5 mg TABLETS PHARMA-Q.

3. How to take LETROZOLE 2,5 mg TABLETS PHARMA-Q

Do not share medicines prescribed for you with any other person.

Always take LETROZOLE 2,5 mg TABLETS PHARMA-Q exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one tablet of LETROZOLE 2,5 mg TABLETS PHARMA-Q taken once a day. Taking LETROZOLE 2,5 mg TABLETS PHARMA-Q at the same time each day will help you remember when to take your tablet.

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

Your doctor will tell you how long your treatment with LETROZOLE 2,5 mg TABLETS PHARMA-Q will last. Do not stop treatment early. If you have the impression that the effect of LETROZOLE 2,5 mg TABLETS PHARMA-Q is too strong or too weak, tell your doctor or pharmacist.

If you take more LETROZOLE 2,5 mg TABLETS PHARMA-Q than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining LETROZOLE 2,5 mg TABLETS PHARMA-Q tablets with you so the doctor will know what you have taken.

If you forget to take LETROZOLE 2,5 mg TABLETS PHARMA-Q

If you have missed your dose of LETROZOLE 2,5 mg TABLETS PHARMA-Q by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take LETROZOLE 2,5 mg TABLETS PHARMA-Q at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses

If you stop taking LETROZOLE 2,5 mg TABLETS PHARMA-Q

Do not stop taking LETROZOLE 2,5 mg TABLETS PHARMA-Q unless your doctor tells you to.

If you stop taking LETROZOLE 2,5 mg TABLETS PHARMA-Q too early, there is a risk of your breast cancer coming back.

4. Possible side effects

LETROZOLE 2,5 mg TABLETS PHARMA-Q can have side effects.

Not all side effects reported for LETROZOLE 2,5 mg TABLETS PHARMA-Q are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LETROZOLE 2,5 mg TABLETS PHARMA-Q, please consult your health care provider for advice.

If any of the following happens, stop taking LETROZOLE 2,5 mg TABLETS PHARMA-Q and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling mainly of the face and throat and/or swelling of the hands, feet, ankles, lips and mouth, which may cause difficulty in swallowing or breathing, (signs of allergic reaction),
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder).

These are all very serious side effects. If you have them, you may have had a serious reaction to LETROZOLE 2,5 mg TABLETS PHARMA-Q. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- weakness, paralysis or loss of feeling in any part of the body (particularly arm or leg), loss of coordination, nausea, or difficulty speaking or breathing (sign of a brain disorder, e.g. stroke),

- sudden oppressive chest pain (sign of a heart disorder),
- swelling and redness along a vein which is extremely tender and possibly painful when touched,
- severe fever, chills or mouth ulcers due to infections (lack of white blood cells),
- severe persistent blurred vision,
- difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm, leg or foot pain (signs that a blood clot may have formed).
- yellow skin and eyes, nausea, loss of appetite, dark-coloured urine (signs of hepatitis),

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- hot flushes,
- increased level of cholesterol (hypercholesterolaemia),
- fatigue,
- increased sweating,
- pain in bones and joints (arthralgia),
- skin rash,
- headache,
- dizziness,
- malaise (generally feeling unwell),
- gastrointestinal disorders such as nausea, vomiting, indigestion, constipation, diarrhoea,
- increase in or loss of appetite,
- pain in muscles,
- thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases,
- swelling of arms, hands, feet, ankles (oedema),
- depression,

- weight increase,
- hair loss,
- raised blood pressure (hypertension),
- abdominal pain,
- dry skin,
- vaginal bleeding,
- palpitations, rapid heart rate,
- joint stiffness (arthritis),

Less frequent

- nervous disorders such as anxiety, nervousness, irritability, drowsiness, memory problems, somnolence, insomnia,
- heart failure
- chest pain
- pain or burning sensation in the hands or wrist (carpal tunnel syndrome),
- impairment of sensation, especially that of touch,
- tendon pain or swelling,
- eye disorders such as blurred vision, eye irritation,
- skin disorders such as itching (urticaria),
- vaginal discharge or dryness,
- breast pain,
- fever,
- thirst, taste disorder, dry mouth,
- dryness of mucous membranes,
- weight decrease,
- urinary tract infection, increased frequency of urination,
- cough,

- increased level of enzymes,
- yellowing of the skin and eyes,
- high blood levels of bilirubin (a breakdown product of red blood cells).

Frequency not known:

- trigger finger, a condition in which your finger or thumb catches in bent position.
- swelling and welts on the surface of the skin, which may or may not itch, abdominal cramping, a swollen throat, hoarseness, and difficulty breathing (signs of an illness called angioedema).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reactions & Quality Problem Reporting Form”, found online under SAHPRA’s publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf

By reporting side effects, you can help provide more information on the safety of LETROZOLE 2,5 mg TABLETS PHARMA-Q.

5. How to store LETROZOLE 2,5 mg TABLETS PHARMA-Q

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep blisters in the outer carton until required for use.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LETROZOLE 2,5 mg TABLETS PHARMA-Q contains

- The active substance is letrozole.

Each film-coated tablet contains 2,5 mg letrozole.

Contains sugar: lactose monohydrate 85 mg per tablet.

- The other ingredients are:

Tablet core: croscarmellose sodium, lactose monohydrate, magnesium stearate, povidone, silica colloidal anhydrous.

Tablet coating: Opadry yellow 03B82401 (hypromellose, E464, titanium dioxide, E171, iron oxide yellow, E172, macrogol 400 and talc, E553b)

What LETROZOLE 2,5 mg TABLETS PHARMA-Q looks like and contents of the pack

Dark yellow coloured, round shaped, slightly biconvex bevel edged film coated tablets debossed with '5' on one side and 'H' on the other side.

Blister packs of 10 tablets per blister, packed in aluminium/clear PVC/PE/PVDC blisters or Alu-Alu blisters

30 tablets are packed in an outer carton.

Holder of Certificate of Registration

Pharma-Q Holdings (Pty) Ltd

50 Commando Road

Industria West 2003

Johannesburg

South Africa

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Access to the corresponding Professional Information

To follow