Viobrest® 2.5mg Film-coated tablets
Letrozol

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT Viobrest IS AND WHAT IT IS USED FOR
Letrozole 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 reduces the amount of oestrogen by blocking an enzyme (aromatase) involved in the production of oestrogens. As a consequence tumour cells slow or stop the growing and/or spreading to other parts of the body.
Letrozole is used to prevent breast cancer happening again. It can be used as a first treatment after breast surgery or following five years of treatment with tamoxifen.
Letrozole is also used to prevent breast tumour spreading to other parts of the body in patients with advanced disease.
Letrozole should only be used for
- oestrogen receptor-positive breast cancer and
- only in women after menopause i.e. cessation of periods.

2. BEFORE YOU TAKE Viobrest
Do not take Viobrest
- if you are allergic (hypersensitive) to letrozole or to any of the other ingredients of Viobrest (see section 6, What Viobrest contains).
- if you still have periods, i.e. if you have not yet gone through the menopause.
- if you are pregnant.
- if you are breast-feeding.

Take special care with Viobrest
- if you suffer from a disorder or disease which affects your liver or kidneys.
- if you have a history of osteoporosis or bone fractures. Letrozole may cause thinning or wasting of your bones (osteoporosis) due to the reduction of oestrogens in your body. Your doctor may therefore decide to measure your bone density before, during and after treatment. Your doctor can give you medicine to prevent or treat the bone loss.

If any of these conditions apply to you, contact your doctor before taking this medicine.

Children and adolescents (below 18 years): Children or adolescents should not use letrozole.

Older people (aged 65 years and over): People aged 65 years and over can use letrozole at the same dose as for other adult.

Taking other medicines
Other medicines may be affected by letrozole. They, in turn, may affect how well letrozole works.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Viobrest with food and drink
Food and drink do not affect letrozole.

Pregnancy and breast-feeding
Letrozole should not be used during pregnancy and breast-feeding as it may harm your baby.
Contact your doctor immediately if you think you are pregnant.
Letrozole is only used to treat breast cancer in post-menopausal women. However, if you recently became postmenopausal or if you are perimenopausal, your doctor should discuss with you about the necessity of a pregnancy test before taking letrozole and of contraception as you might have the potential to become pregnant.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
If you feel dizzy, tired, drowsy or generally unwell, do not drive or operate any tools or machines until you feel normal again.

Important information about some of the ingredients of Viobrest
Letrozole tablets contain the milk sugar lactose. If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicinal product.

3. HOW TO TAKE Viobrest
Always take letrozole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablet should be swallowed whole with a glass of water or another liquid.
The usual dose is one tablet taken once daily.
No dosage adjustment is required for elderly patients or for patients with mild kidney problems.

If you take more Viobrest than you should: If you have taken too much letrozole, or if someone else accidentally took your tablets, contact your doctor, pharmacy or hospital for advice immediately.

If you forget to take Viobrest: Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet at the usual time.

If you stop taking Viobrest: Do not stop taking letrozole even if you are feeling well, unless your doctor tells you. Your doctor will advise you on how long you should continue to take your tablets. You may need to take it for months or even years.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, letrozole can cause side effects, although not everybody gets them.
Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment. Some of these side effects, such as hot flushes, hair loss or vaginal bleeding, may be due to the lack of oestrogens in your body.

Some Side effects could be serious.
These side effects are rare or uncommon, (i.e. occurring in at least 1 in 10,000, but in less than 1 in 100 treated patients).
- if you experience weakness, paralysis or loss of feeling in an arm or leg or any other part of the body, loss of coordination, nausea, or difficulty in speaking or breathing (sign of a brain disorder, e.g. stroke).
- if you have sudden oppressive chest pain (sign of a heart disorder).
- if you experience difficulty in breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm or leg (foot) pain (signs that a blood clot may have formed).
- if you experience swelling and redness along a vein which is extremely tender and possibly painful when touched.
- if you get severe fever, chills or mouth ulcers due to infections (lack of white blood cells).
- if you get severe persistent blurred vision.

If you get any of listed above tell your doctor straight away.

Other side effects can be:

Very common (occurring in at least 1 in 10 treated patients):
- Increased sweating
- Pain in bones and joints (arthralgia)
- Hot flushes, fatigue including weakness or loss of strength

Common (occurring in at least 1 in 100, but in less than 1 in 10 treated patients):
- Increase in or loss of appetite, high level of cholesterol
- Sad mood (depression)
- Headache, dizziness
- Nausea, vomiting, indigestion, constipation, diarrhoea
- Hair loss and skin rash

• Muscle pain, bone pain, thinning or wasting of your bones (osteoporosis), leading to bone fractures in some cases (see also section 2, Before you take Viobrest)
• Weight increase
• Generally feeling unwell (malaise), swelling of arms, hands, feet, ankles (peripheral oedema)

Uncommon (occurring in at least 1 in 1,000, but in less than 1 in 100 treated patients):
• Urinary tract infection
• Tumour pain
• Reduction in the number of white blood cells
• Swelling of body parts (general oedema)
• Anxiety, nervousness, irritability
• Drowsiness, insomnia, memory problems, impairment of sensation (especially that of touch), taste disorder, brain infarction (cerebrovasculair accident)
• Lens opacity (cataract), eye irritation, blurred vision
• Palpitations, rapid heart rate
• Inflammation of the wall of a vein, raised blood pressure, heart problems (ischemic cardiac events)
• Shortness of breath, cough
• Abdominal pain, inflammation of the mucous lining of the mouth, dry mouth
• Increased liver enzymes
• Itching, dry skin, hives
• Joint stiffness
• Increased frequency of urination
• Vaginal bleeding, vaginal discharge or dryness, breast pain
• Fever, dryness of mucous membranes, thirst
• Weight loss

Rare (occurring in at least 1 in 10,000, but in less than 1 in 1,000 treated patients):
• Blood clot in the lung artery (pulmonary embolism), blood clot in the artery (arterial thrombosis), stroke (cerebrovascular infarction)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Viobrest
Keep out of the reach and sight of children.
This medicinal product does not require any special storage conditions.

Do not use Viobrest after the expiry date which is stated on the blister and carton 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What Viobrest contains
• The active substance is letrozole. Each film-coated tablet contains 2.5 mg letrozole.
• The other ingredients are: lactose monohydrate, cellulose microcrystalline (E460), maize starch pregelatinised, sodium starch glycolate, magnesium stearate (E572), colloidal silicon dioxide (E551). The ingredients in the tablet coating are macrogol, talc (E553b), hypromellose (E464), titanium dioxide (E171), iron oxide yellow (E172).

What Viobrest looks like and contents of the pack
Letrozole is a yellow film-coated round tablet, inscripted with L900 at one side and 2.5 on the other side.
Letrozole is available in blisters of 10, 28, 30, 50, 60, 84, 90, 98 or 100 tablets per box.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
MARKETING AUTHORISATION HOLDER: VIOGEN Pharmaceuticals, El. Venizelou Av.309, 176 74 Kallithea, Athens, Greece.

MANUFACTURERS:
Synthon BV
Microweg 22, 6545 CM Nijmegen
The 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 medicinal product is authorised in the Member States of the EEA under the following names:

AT	Letrozol Synthon 2,5 mg Filmtabletten
BE	Letrozol Synthon 2,5 mg
BG	Letrozol Synthon 2,5 mg
CZ	Letromedac 2,5 mg
DE	Letromedac 2,5 mg
DK	Letromedac 2,5 mg
EE	Letrozole SanoSwiss 2,5 mg
EL	Viobrest
ES	Letrozol Cinfamed 2,5 mg comprimidos EFG
FI	Letrolan
FR	Letrozole Synthon 2.5 mg, comprimé pelliculé
HU	Letrozol Synthon 2,5 mg
IE	Letrozole Synthon 2.5 mg, film-coated tablets
IS	Letrozol Synthon 2.5 mg
LT	Letrozole SanoSwiss 2,5 mg plėvele dengtos tabletės
LU	Letrozol Synthon 2,5 mg
LV	Letrozole SanoSwiss 2,5 mg apvalkotās tabletes
NL	Letrozol Synthon 2,5 mg, filmomhulde tabletten
NOα	Letromedac 2,5 mg
PL	Letromedac
PT	Letrozol medac
RO	Letrozol Synthon 2,5 mg
SE	Letromedac
SI	Letrozol Synthon 2,5 mg filmsko obložene tablete
SK	Letromedac 2,5 mg

This leaflet was last approved in {07/10}.

General classification for supply

Subject to medical prescription.

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pharmaceuticals