Femaplex®

1.1. Trade Name: FEMAPLEX

1.2. Composition: ***Active substance:*** Letrozole. ***Excipients:*** Lactose monohydrate (Spray Dried), Microcrystalline cellulose, Maize starch, Sodium starch glycolate (Type A), Silica colloidal anhydrous, Magnesium Stearate. ***Coating:*** Opadry yellow 02B38014 which contains: Titanium dioxide E171, Yellow iron oxide E172, Macrogol 4000, Red iron oxide E172, Talc, Hypromellose 5cP.

1.3. Pharmaceutical Form: Film-coated tablets

1.4. Content in active substance: Each tablet contains letrozole 2.5mg

1.5. Package description: Package containing 3 blisters of 10 tablets.

1.6. Pharmacotechnical class: Antagonists to hormones

1.7. Marketing Authorization Holder: GENEPHARM S.A. - 18 km Marathon Avenue, GR-153 51 Pallini, Attica- Greece

1.8. Manufacturer-Packager: GENEPHARM S.A. - 18 km Marathon Avenue. GR-153 51 Pallini, Attica- Greece

2. WHAT YOU NEED TO KNOW ABOUT THE DRUG YOUR DOCTOR PRESCRIBED YOU

The information included in this leaflet regards only the specific drug your doctor prescribed you.
You are kindly requested to read it carefully. You will find significant information though not everything is explained. Should you have any queries, or if you are not sure about something, consult your doctor or your pharmacist.

2.1 General Information

FEMAPLEX is used for breast cancer treatment in post-menopausal women previously subject to treatment with anti-estrogens (e.g. tamoxifen, inhibiting estrogens influence).
This applies in patients with artificially-induced and natural menopause. FEMAPLEX is a well known aromatase inhibitor. It acts by decreasing the influence of estrogens (sex hormone) in the body. Estrogens may stimulate growth of various breast cancer types.

2.2 Indications

First line treatment in post-menopausal women with advanced hormone-dependent breast cancer.
It is recommended in advanced breast cancer treatment in women with natural or artificially-induced menopause after a disease recurrence or evolution, previously subject to anti-estrogens treatment.
Efficacy in patients with negative estrogens receptors has not been evidenced.

2.3 Contraindications

Before taking FEMAPLEX it is important to inform your physician if you have other medical problems or if you take other drugs
Make sure your physician knows:
If you previously suffered from any unusual or allergic reactions to letrozole or to any of its ingredients
If you still have menstruation.
If you are pregnant or breast-feeding.
If the answer to any of the above is YES, FEMAPLEX is not recommended for you.

2.4 Special warnings and precautions during use

General information: You must also inform your physician if you suffer from:
• Severe renal failure
• Hepatic failure
Your physician will take it into consideration before and during treatment with FEMAPLEX.
Use in children: FEMAPLEX is not intended for pediatric use.

2.4.1 Use in elderly people

Dosage readjustment is not necessary for elderly patients.

2.4.2 Use during pregnancy

FEMAPLEX is contra-indicated during pregnancy.

2.4.3 Use during breast-feeding

FEMAPLEX is contra-indicated during the breast-feeding period.

2.4.4 Effect on the ability to drive and operate machinery

Fatigue or dizziness has been reported in some cases. Should this happen to you, avoid driving or operating machinery or performing other duties requiring full alertness.

2.5 Interactions with other drugs or substances or other forms of interaction
To date there is no experience in co-administration of FEMAPLEX with other antineoplastic drugs.
Attention is required in concomitant administration of FEMAPLEX with drugs whose metabolism depends on the isoenzymes 2A6 and 2C19 of cytochrome P450 and with a non broad therapeutic indicator.
To date there have not been reports of adverse events when FEMAPLEX is being taken with other drugs. You must consult your physician prior to taking other drugs during treatment with FEMAPLEX.

2.6 Dosage and route of administration
FEMAPLEX recommended dose is 2,5mg: a tablet taken orally once daily. The tablet must be swollen with a little liquid. Your physician will decide FEMAPLEX treatment duration.
In children: FEMAPLEX is not for pediatric use.
Patients with hepatic or/and renal failure: No dosage adjustment is required in patients with renal failure and creatinine clearance greater than 30mL/min.
There are sufficient data for cases of renal failure with creatinine clearance lower than 30mL/ min or in patients with severe hepatic failure.

2.7 Overdose - Management
FEMAPLEX is well tolerated even in higher dosage. However, in the event of overdose you need to contact your physician or pharmacist immediately.

2.8 Adverse Events
As with any drug, FEMAPLEX may cause some adverse events (side effects). Many adverse events have been reported to be mild to moderate and very rarely quite severe leading to FEMAPLEX treatment discontinuation. Many adverse events may be brought about due to your disease or to hormonal production in your body (such as flushing, hair loss).
Adverse events may not occur; but should they occur, they might need medical care. Consult your physician if adverse events do not subside during treatment or if they are disturbing.
Possible adverse events are: dizziness, headache, thrombophlebitis, oedema due to fluid retention, weight gain, loss of weight, fatigue, nausea, vomiting, dyspepsia, increase or decrease of appetite, constipation, flushing, hair loss, alopecia, rash, musculoskeletal pains (e.g. arms, tibiae, back), vaginal bleeding, vaginal discharge, dyspnea, changes in lymphocytes measurements and increase of aminotransferases.
Should you observe any other adverse events not mentioned above, consult your physician, the nurse or your pharmacist.

2.9 What you should know in case you missed a dose.
If you forgot to take a dose of FEMAPLEX, do not worry; take the missing dose once you realize it. However, if it is almost time to take the following dose, continue with the regular dosage without taking the missing one. Do not double dosage.

2.10 Product expiry date
It is written inside and outside the package.
If this date has elapsed, the product should not be used.

2.11 Special precautions for product storage
To be stored in temperature below 25°C.

3. INFORMATION ON THE RATIONAL USE OF DRUGS
- This drug was prescribed to you by your physician only for your particular medical problem. It should not be administered to other patients neither be used for any other condition, without previously consulting your physician.
- Should any problem occur with the drug during treatment, inform immediately your physician or your pharmacist.
- Should you have any questions on the drug-related information you receive, or if you need more information about your medical problem, do not hesitate to request this information from your physician or your pharmacist.
- For reasons of safety and efficacy, the drug should be taken according to the instructions given.
- For your health and safety, it is necessary to read carefully every piece of information relating to the drug administered.
- Do not keep the drugs in the bathroom because heat and humidity may cause deterioration making them harmful for human health.
- Do not keep drugs you no longer need or drugs that have expired.
- Keep the drugs at a safe place, inaccessible to children. Your drugs may harm children.

4. This drug is a prescription only medicine (POM).

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