PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

FASLODEX®

SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE

For intramuscular injection

Composition:

Each pre-filled syringe (5 ml) contains:

Fulvestrant 250 mg

For the list of inactive ingredients in the preparation, see section 2 "Important information regarding some of the medicine ingredients" and section 6 - "Further Information".

Read the leaflet carefully in its entirety before using the medicine.

Keep the leaflet; you may need it again.

This leaflet contains concise information about the medicine. If you have further questions, please refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

- Faslodex is indicated for the treatment of oestrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with hormonal therapy, or with disease relapse/progression on or after adjuvant endocrine therapy.
- Faslodex, in combination with the preparation palbociclib, is intended for women with advanced or metastatic estrogen receptor-positive and HER2-negative breast cancer, whose disease has progressed after receiving prior hormonal treatment for this ailment.

When used in combination with palbociclib (Ibrance), please read the palbociclib (Ibrance) patient package insert as well.

Therapeutic group:

Estrogen antagonist.

Faslodex contains the active ingredient fulvestrant, which belongs to the group of medicines that block the activity of estrogen. Estrogen is a female sex hormone, that can, in some cases, be involved in development of breast cancer.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive to fulvestrant or to any of the other ingredients of this medicine (detailed in

section 6).
- You are pregnant or breastfeeding.
- You have severe liver problems.

Special warnings regarding use of Faslodex

Before treatment with the medicine, tell the doctor if you have:

- Kidney or liver problems.
- Previous blood clotting problems.
- A low platelet (help in blood clotting) count or bleeding disorders.
- Osteoporosis (bone thinning).
- Alcohol addiction (alcoholism).
- This preparation may disrupt the results of tests that measure estradiol levels. Whenever you refer for laboratory tests, inform the doctor that you are taking Faslodex.

Children and adolescents

Faslodex is not indicated for use in girls and adolescents under 18 years of age.

! Drug interactions

If you are taking other medicines

Tell the doctor or pharmacist if you are taking:

Please inform the attending doctor if you are concomitantly taking additional medicines or if you have just finished treatment with another medicine, including non-prescription medicines, vitamins, nutritional supplements and herbal medicines. This is because Faslodex may affect the way certain medicines work and certain medicines may affect the way Faslodex works. Especially if you are taking anti-coagulants.

! Pregnancy and breastfeeding

- **Pregnancy:**

Do not use Faslodex if you are pregnant. If you are of child-bearing age and may become pregnant, you must use an effective contraceptive method during the course of treatment with Faslodex and for 2 years after your last dose.

- **Breastfeeding:**

Do not breastfeed during the course of treatment with Faslodex.

! Driving and use of machinery

Faslodex should not affect your ability to drive or to operate machinery. If you feel tired after treatment, do not drive or operate machinery.

! Important information regarding some of the medicine ingredients:

Faslodex contains 10% w/v (weight per volume) ethanol (alcohol), for example, a 500 mg alcohol per dose is equivalent to 10 ml of beer or 4 ml of wine. This quantity can be harmful to people suffering from alcoholism. Take this into consideration at-risk people, such as patients with liver disease or epilepsy.

Faslodex contains 500 mg benzyl alcohol per injection, equivalent to 100 mg/ml. Benzyl alcohol may cause allergic reactions.

Faslodex contains 750 mg benzyl benzoate per injection, equivalent to 150 mg/ml.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The doctor will explain to you how to take the medicine (the dose and time of injection). The strength and duration of treatment are determined by the doctor, depending on the disease from which you are suffering from.

The usual dosage, unless instructed otherwise by the doctor, is:

The usual dose is 500 mg fulvestrant (2 injections of 250 mg/5 ml), given once a month, with an additional 500 mg dose, given two weeks after the first dose.

- When fulvestrant is given in combination with Ibrance, the usual dosage of fulvestrant is 500 mg on days 1, 15 and 29, and once a month thereafter. Refer to the Ibrance patient package insert.

Instructions for use

Your doctor or nurse will inject **Faslodex**, as a slow, intramuscular injection. One injection to each side of the buttocks.

If you accidentally took a higher dosage, or if a child accidentally swallowed the medicine, refer to a doctor immediately or proceed to a hospital emergency room and bring the package of the medicine with you.

Complete the treatment recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Be sure to follow the instructions for taking the medicine accurately and to ask the doctor if there is any doubt.

If you have any further questions regarding the use of this medicine, consult with your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Faslodex may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects that require special attention:

If the following side effects occur, you may need emergency medical attention:

Faslodex as a monotherapy:

- Hypersensitivity (allergic) reaction, including swelling of the face, lips, tongue and/or throat. These may be signs of anaphylactic reactions.
- Thromboembolism - increased risk of blood clots*.
- Inflammation of the liver (hepatitis).
- Liver failure.

Faslodex in combination with palbociclib:

- Pulmonary embolism.

Inform your doctor or pharmacist if the following side effects occur:

Very common side effects (affect more than 1 in 10 patients):

Faslodex as monotherapy:

- Injection site reactions, such as pain and/or inflammation.
- Abnormal levels of liver enzymes (in blood tests)*.
- Nausea.
- Weakness.
- Tiredness*.
- Joint and musculoskeletal pain.
- Hot flushes.
- Skin rash.
- Hypersensitivity (allergic) reaction, including swelling of the face, lips, tongue and/or throat.

Additional side effects:

Common side effects (affect up to one in 10 patients):

- Headache.
- Vomiting, diarrhea or loss of appetite*.
- Urinary tract infection.
- Back pain*.
- Thromboembolism - increased risk of blood clots*.
- Increase of bilirubin (bile pigment produced by the liver).
- Reduced blood platelet count (thrombocytopenia).
- Vaginal bleeding.
- Lower back pain radiating to leg on one side (sciatica).

- Sudden weakness, numbness, tingling, or loss of movement in your leg, especially on only one side of your body, sudden problems with walking or balance (peripheral neuropathy).

Faslodex in combination with palbociclib

Very common side effects (occur in at least one in ten patients):

- Reduced white blood cell count (neutropenia, leukopenia).
- Infections.
- Tiredness.
- Nausea, vomiting.
- Anemia.
- Inflammation in the mouth (stomatitis).
- Headache.
- Diarrhea.
- Reduced blood platelet count (thrombocytopenia).
- Constipation.
- Balding.
- Rash.
- Reduced appetite.
- Fever.

Additional side effects:

- Weakness.

Faslodex as monotherapy

Uncommon side effects (affect up to one in 100 patients):

- Thick, white vaginal discharge and fungal infection.
- Bruising, bleeding at the injection site.
- Elevated level of liver enzymes called gamma GT (in blood tests).
- Inflammation of the liver (hepatitis).
- Liver failure.
- Tingling, numbness and pain.
- Anaphylactic reaction

* Includes side effects whose influence of Faslodex is unclear due to an underlying disease.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not induce vomiting without explicit instruction from the doctor!
- Store between 2ºC-8ºC (in a refrigerator).
- Store Faslodex in the original package to protect from light.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. In any case of doubt, consult the pharmacist who dispensed the medicine to you.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Benzyl benzoate, benzyl alcohol, ethanol 96%, castor oil.

What the medicine looks like and contents of the pack

- Faslodex is a clear-transparent to yellowish, viscous solution for injection in a pre-filled syringe with a safety latch.
- Each package contains two pre-filled glass syringes and safety needles (BD SafetyGlide™) to be connected to the syringe.

Manufacturer:

AstraZeneca UK Ltd.,

Macclesfield, United Kingdom.

License holder and importer:

AstraZeneca (Israel) Ltd.,

1 Atirei Yeda St. Kfar Saba 4464301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health

132 67 31114

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