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

This medicine is dispensed with a doctor's prescription only

Fulvestrant Rompharm
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, 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?

- Fulvestrant Rompharmis indicated for the treatment of estrogen 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.
- Fulvestrant Rompharm, in combination with the preparation Palbociclib or Abemaciclib, 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.
- Fulvestrant Rompharm, in combination with Ribociclib, is intended for men and postmenopausal women with advanced or metastatic estrogen receptor-positive and HER2-negative breast cancer, whose disease has progressed after receiving prior endocrine treatment for this ailment or as initial endocrine treatment.

When used in combination with Palbociclib (Ibrance), Abemaciclib (Verzenio) or Ribociclib (Kisqali) please read the Palbociclib (Ibrance), Abemaciclib (Verzenio) or Ribociclib (Kisqali) patient package insert as well.

Therapeutic group:
Estrogen antagonist.
Fulvestrant Rompharm 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 the 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 the use of Fulvestrant Rompharm
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 Fulvestrant Rompharm.

Children and adolescents
Fulvestrant Rompharm 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 Fulvestrant Rompharm may affect the way certain medicines work and certain medicines may affect the way Fulvestrant Rompharm works. Especially if you are taking anti-coagulants.

Pregnancy and breastfeeding

- **Pregnancy:**

Do not use Fulvestrant Rompharm 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 Fulvestrant Rompharm and for 2 years after your last dose.

- **Breastfeeding:**

Do not breastfeed during the course of treatment with Fulvestrant Rompharm.

Driving and use of machinery
Fulvestrant Rompharm should not affect your ability to drive or to operate machinery. If you feel tired after treatment, do not drive or operate machinery.
The amount of alcohol in this medicinal product may impair your ability to drive or use machines.

Important information regarding some of the medicine ingredients:
Fulvestrant Rompharm contains 12.4% v/v (volume per volume) ethanol (alcohol), i.e. up to 1,000 mg per dose, equivalent to 25 ml beer or 10 ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy. The amount of alcohol in this medicinal product may alter the effects of other medicines.

Fulvestrant Rompharm contains 500 mg benzyl alcohol per injection, equivalent to 100 mg/ml. Benzyl alcohol may cause allergic reactions.
Fulvestrant Rompharm 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 dosage and treatment regimen will be determined only by the doctor.
Do not exceed the recommended dose.

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 Rompharm is given in combination with Ibrance, Verzenio or Kisqali, the usual dosage of Fulvestrant Rompharm is 500 mg on days 1, 15 and 29, and once a month thereafter. Refer to the Ibrance, Ver- zenio or Kisqali patient package insert.

Instructions for use
Your doctor or nurse will inject **Fulvestrant Rompharm,** 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.
Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

4. SIDE EFFECTS

As with any medicine, the use of Fulvestrant Rompharm 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:
Fulvestrant Rompharm may cause serious side effects, including:

- **Injection site related nerve damage.** If you develop any of the following symptoms in your legs following a Fulvestrant Rompharm injection, please refer to your doctor:
    - Numbness.
    - Tingling.
    - Weakness.

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

- 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.

Inform your doctor, nurse or pharmacist if the following side effects occur: Very common side effects (affect more than 1 in 10 patients):
- 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) reactions, including swelling of the face, lips, tongue and/or throat.
- Cough.
- Constipation.

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*.
- Increase of bilirubin (bile pigment produced by the liver).
- Thromboembolism - increased risk of blood clots*.
- Reduced blood platelet count (thrombocytopenia).
- Vaginal bleeding.
- Lower back pain irradiating 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).
- Pain in arms, hands, legs, or feet.
- Shortness of breath.

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 (allergic) reaction.

* Includes side effects whose influence of Fulvestrant Rompharm 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 2°C-8°C (in a refrigerator).
- Store Fulvestrant Rompharm 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 the contents of the pack

- Fulvestrant Rompharm is a clear, colourless to yellow, practically free from visible particle, oily and viscous solution, in a glass pre-filled syringe. Each syringe contains 5 ml solution for injection.
- Each package contains two pre-filled glass syringes and safety needles (BD SafetyGlideTM) to be connected to the syringe.

Manufacturer:
Rompharm Company S.R.L, 1A Eroilor Street, 075100 Otopeni, jud. Ilfov, Romania

License holder:
A.L. Medi-Market ltd., 3 Hakatif St., Emek Hefer Industrial Park, 3877701

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
175-98-37067-99

Revised in August 2024.