Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Fulvestrant Teva

Solution for injection in a pre-filled syringe
For intramuscular injection

Active ingredient:
Each pre-filled syringe (5 ml) contains:
Fulvestrant 250 mg
Inactive ingredients and allergens: see section 2 under - 'Important information about some of this medicine's ingredients', and section 6 - 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.
Keep the leaflet; you may need it again.
This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

- Fulvestrant Teva is indicated for the treatment of estrogen receptor positive, 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 Teva, in combination with the preparation palbociclib, is indicated 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 Fulvestrant Teva is used in combination with palbociclib, please read the palbociclib patient information leaflet as well.
Therapeutic group: Estrogen antagonist.
Fulvestrant Teva 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 this medicine

Do not use this medicine if:

- You are sensitive (allergic) to fulvestrant or to any of the other ingredients that this medicine contains (see section 6).
- You are pregnant or breastfeeding.
- You have severe liver problems.

Special warnings regarding use of Fulvestrant Teva
Before using the medicine, tell your doctor if you have:
- Kidney or liver problems.
- Previous blood clotting problems.
- A low blood 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 are referred for laboratory tests, inform the doctor that you are taking Fulvestrant Teva.

Children and adolescents
Fulvestrant Teva is not indicated for use in young and adolescent girls under 18 years of age.

Interactions with other medicines
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist. This is because Fulvestrant Teva may affect the way certain medicines work, and certain medicines may affect the way Fulvestrant Teva works. Especially if you are taking anticoagulants.

Pregnancy and breastfeeding
Pregnancy:
Do not use Fulvestrant Teva if you are pregnant. If you are of childbearing age and may become pregnant, you must use effective contraceptive methods during the course of treatment with Fulvestrant Teva and for 2 years after receiving the last dose of treatment.
Breastfeeding:
Do not breastfeed during the course of treatment with Fulvestrant Teva.

Driving and using machines
Fulvestrant Teva should not affect your ability to drive or to operate machines. If you feel tired after treatment, do not drive or operate machines.

Important information about some of this medicine's ingredients
Fulvestrant Teva contains about 10% w/v (weight per volume) ethanol (alcohol) in each pre-filled injection syringe (5 ml), equivalent to about 100 mg/ml alcohol. The quantity in one Fulvestrant Teva dose (10 ml) is equivalent to about 20 ml of beer or 8 ml of wine. This quantity can be harmful to people suffering from alcoholism. Take this into consideration in women at risk, such as patients with liver disease or epilepsy.
Fulvestrant Teva contains 500 mg benzyl alcohol in each pre-filled injection syringe (5 ml), equivalent to 100 mg/ml. Benzyl alcohol may cause allergic reactions. Consult your doctor or pharmacist if you have a liver or kidney disease, since large quantities of benzyl alcohol can accumulate in your body and may cause side effects ("metabolic acidosis").
Fulvestrant Teva contains 750 mg benzyl benzoate in each pre-filled injection syringe (5 ml), equivalent to 150 mg/ml.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. 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 palbociclib, the usual dosage of fulvestrant is 500 mg on days 1, 15 and 29, and once a month thereafter. Refer to the palbociclib patient leaflet.

Do not exceed the recommended dose

Manner of use
Your doctor or nurse will inject you with Fulvestrant Teva as a slow, intramuscular injection. One injection to each side of the buttocks.
If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you**.**

Follow the treatment as recommended by your doctor.
Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor.
Be sure to follow the dosing instructions very carefully and to ask the doctor if there is any doubt.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them. If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Fulvestrant Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Side effects that require special attention: If the following side effects occur, you may need urgent medical attention:
Fulvestrant as monotherapy:
- Hypersensitivity reaction (allergy), including swelling of the face, lips, tongue and/or throat. These effects may be signs of anaphylactic reactions.
- Thromboembolism - increased risk of blood clots*.
- Inflammation of the liver (hepatitis).
- Liver failure.

Fulvestrant in combination with palbociclib:
- Pulmonary embolism

Inform your doctor or pharmacist if the following side effects occur:
Very common side effects (affect more than one in 10 patients):
Fulvestrant as monotherapy:
- Injection site reactions, such as pain and/or inflammation.
- Abnormal levels of liver enzymes (in blood tests)*.
- Nausea.
- Weakness.
- Tiredness*.
- Joint, muscle and bone pain.
- Hot flushes.
- Skin rash.
- Hypersensitivity reaction (allergy), 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 the 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).

Fulvestrant in combination with palbociclib
Very common side effects (occur in at least one in 10 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.

Fulvestrant 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 (allergic) reaction.

* Side effects in which the influence of Fulvestrant is unclear due to the underlying disease.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! This and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not induce vomiting unless explicitly instructed to do so by a doctor!

Storage conditions:
- Store in a refrigerator (2ºC-8ºC).
- Store the pre-filled syringes in the original package to protect from light.
- The syringes can be stored out of the refrigerator and below 25ºC for a period of up to 28 days. The syringes cannot be returned to the refrigerator. Discard them at the end of the period of storage out of the refrigerator.
- Do not use the medicine after the expiry date (exp. date) which 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.
- The pre-filled syringe is intended for single use.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Benzyl benzoate, benzyl alcohol, ethanol 96%, castor oil refined

What the medicine looks like and contents of the package
A pre-filled syringe fitted with a Luer-Lock connector. The syringe contains 5 ml of a viscous, clear, colourless to yellow solution. Each package contains one or two syringes, as well as safety needle/s for connection to the syringe barrel/s.
Not all pack sizes may be marketed.

Name and address of the manufacturer and license holder:
Teva Israel Ltd., 124 Dvora Hanevi'a St., Tel Aviv 6944020

The leaflet was revised in July 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry 161903505300

DOR-Ful-PIL-0723-06

teva

The following information is intended for healthcare professionals only:

Fulvestrant Teva 500 mg (2 x 250 mg/5 ml solution for injection) should be administered using two pre-filled syringes.

Instructions for administration

Administer the injection according to the local guidelines for performing large volume intramuscular injections.

NOTE: Due to the proximity of the underlying sciatic nerve, caution should be taken if administering Fulvestrant Teva at the dorsogluteal injections site.

Warning - **Do not** autoclave safety needle before use. Hands **must** remain behind the needle at all times during use and disposal.

For each of the two syringes:

- Remove glass syringe barrel from tray and check that it is not damaged.
- Peel open the safety needle outer packaging.
- Parental solutions must be inspected visually for particulate matter and discolouration prior to administration.
- Hold the syringe upright on the ribbed part (C). With the other hand, take hold of the cap (A) and carefully twist the cap counter-clockwise until the cap disconnects for removal (see Figure 1).

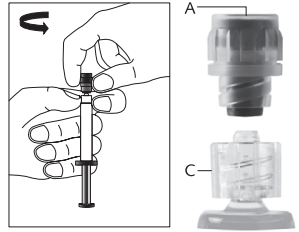

Figure 1

- Remove the cap (A) off in a straight upward direction. To maintain sterility DO NOT TOUCH THE STERILE SYRINGE TIP (Luer-Lock) (B) (see Figure 2).

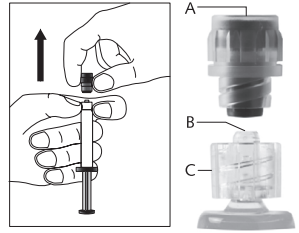

Figure 2

- Attach the safety needle to the Luer-Lock and twist until firmly seated (see Figure 3).
- Check that the needle is locked to the Luer connector before moving out of the vertical plane.
- Transport filled syringe to point of administration.
- Pull shield straight off needle to avoid damaging needle point.

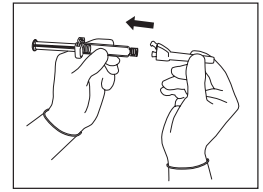
Figure 3

- Expel excess gas from the syringe.
- Administer intramuscularly slowly (1-2 minutes/ injection) into the buttock (gluteal area). For user convenience, the needle bevel-up position is oriented to the lever arm (see Figure 4).

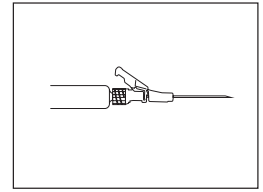
Figure 4

- After injection, immediately apply a single-finger stroke to the activation assisted lever arm to activate the needle shielding mechanism (see Figure 5). NOTE: Activate away from self and others. Listen for click and visually confirm needle tip is fully covered.

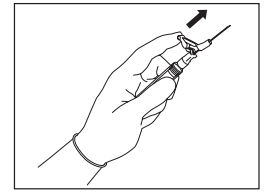
Figure 5

Disposal

Pre-filled syringes are for single use **only**.

This medicine may pose a risk to the aquatic environment. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.