Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Fulvestrant Sandoz®

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

Composition:
Each pre-filled syringe (5 ml) contains:
fulvestrant 250 mg
Each ml contains: fulvestrant 50 mg

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

Read the entire leaflet carefully 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 contact the 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.

1. What is the medicine intended for?

- Fulvestrant Sandoz is 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 Sandoz, in combination with the medicine 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 therapy for this disease.

When Fulvestrant Sandoz is used in combination with palbociclib, please read the patient leaflet for palbociclib as well.

Therapeutic group:
Estrogen antagonist.

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

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient fulvestrant or to any of the other ingredients in this medicine (detailed in section 6).
- You are pregnant or breastfeeding.
- You have severe liver problems.

Special warnings regarding the use of Fulvestrant Sandoz
Before treatment with the medicine, tell the doctor if you have:
- Kidney or liver problems.
- Previous blood clotting problems.
- Low level of platelets (help with blood clotting) or bleeding disorders.
- Osteoporosis (bone thinning).
- Alcohol addiction (alcoholism).
- This medicine may disrupt the results of tests measuring estradiol levels. Whenever you are referred for laboratory tests, inform the doctor that you are taking Fulvestrant Sandoz.

Children and adolescents
Fulvestrant Sandoz is not indicated for use in girls and adolescents under 18 years.

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

Pregnancy and breastfeeding
- **Pregnancy:**
  Do not use Fulvestrant Sandoz if you are pregnant. If you are of childbearing age and may become pregnant, you must use an effective contraceptive method during the period of treatment with Fulvestrant Sandoz and for 2 years after the last dose of treatment.
- **Breastfeeding:**
  Do not breastfeed during the period of treatment with Fulvestrant Sandoz.

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

Important information regarding some of the medicine ingredients:
Fulvestrant Sandoz contains about 10% w/v (weight per volume) ethanol (alcohol) in each pre-filled syringe (5 ml), equivalent to about 100 mg/ml alcohol. The alcohol quantity in one dose of Fulvestrant Sandoz (10 ml, i.e. 2 pre-filled syringes) is equivalent to about 20 ml of beer or about 8 ml of wine. This quantity can be harmful to people suffering from alcohol addiction. This should be taken into consideration in women belonging to a risk group, such as patients with liver disease or epilepsy.
Fulvestrant Sandoz contains 500 mg benzyl alcohol in each pre-filled syringe (5 ml), equivalent to 100 mg/ml. Benzyl alcohol may cause allergic reactions.
Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called metabolic acidosis).
Fulvestrant Sandoz contains 750 mg benzyl benzoate in each pre-filled syringe (5 ml), equivalent to 150 mg/ml.

3. How should you use the medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.
The doctor will explain to you how to take this medicine (the dose and time of injection). The strength and duration of treatment are determined by the doctor, depending on the disease 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. Read the patient leaflet of palbociclib.

Do not exceed the recommended dose.

Instructions for use
Your doctor or nurse will inject you with Fulvestrant Sandoz by 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.
Adhere to the treatment as recommended by the doctor.
Even if your health improves, do not stop taking this medicine without consulting the doctor.
Make 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 about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Fulvestrant Sandoz 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 requiring special attention:
If the following side effects occur, you may need urgent medical attention:
Fulvestrant Sandoz as a monotherapy:
- Hypersensitivity (allergic) reaction, 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 Sandoz 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 Sandoz 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).
- Decreased blood platelet levels (thrombocytopenia).
- Vaginal bleeding.
- Lower back pain radiating to the leg on one side (sciatica).
- Sudden weakness, numbness, tingling, or loss of movement in your legs, especially on only one side of your body, a sudden problem with walking or balance (peripheral neuropathy).

Fulvestrant Sandoz 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.
- Alopecia.
- Rash.
- Reduced appetite.
- Fever.

Additional side effects:
- Weakness.

Fulvestrant Sandoz 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

* Includes side effects in which the influence of Fulvestrant Sandoz 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
Side effects can be reported to the Ministry of Health by clicking 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 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 in a refrigerator (2ºC-8ºC).
- Store Fulvestrant Sandoz 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
- Fulvestrant Sandoz is a clear, colorless to yellow viscous solution for injection in a pre-filled syringe.
- Each package contains two pre-filled syringes and safety needles (BD SafetyGlide®) to be attached to each syringe.

License holder and importer's name and address:
Novartis Israel Ltd., P.O.Box 7126, Tel Aviv

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
167 58 36012 00

Revised in March 2022 according to MOH guidelines.

FUL APL MAR2022 V1 DOR-Ful-PIL-0322-05

The following information is intended for healthcare professionals only:
Instructions for administration

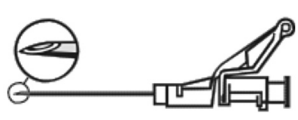
Administer the injection according to the local guidelines for performing large volume intramuscular injections.

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

Warning – Do not autoclave safety needle before use. Hands must remain behind the needle at all times during use and disposal.
Syringes are supplied with safety needle BD SafetyGlide®.

For each of the two syringes:
- Carefully remove the needle and syringe from the packaging.
- Remove the protective cap from the tip of the syringe barrel.
- Peel open the safety needle (BD SafetyGlide) outer packaging. Attach the safety needle to the Luer-Lock.
- Twist to lock the needle to the Luer connector. Twist until firmly seated.
- Pull shield straight off needle to avoid damaging needle point.

- Remove needle sheath.
- While holding the syringe with the needle pointing upward, gently push in the plunger until the medicine is up to the top of the syringe. There should be no air within the barrel.
- Administer intramuscularly slowly (1-2 minutes/injection) into the buttock. For user convenience, the needle bevel-up position is oriented to the lever arm.



- After injection, immediately apply a single-finger stroke to the activation assisted lever arm to activate the shielding mechanism.

NOTE: Activate away from self and others. Listen for click and visually confirm needle tip is fully covered.

Disposal
Pre-filled syringes are for single use **only.**
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.