Package leaflet: Information for the User

Fulvestrant EVER Pharma 250 mg solution for injection in pre-filled syringe

fulvestrant

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fulvestrant EVER Pharma is and what it is used for

Fulvestrant EVER Pharma contains the active substance fulvestrant, which belongs to the group of estrogen blockers. Estrogens, a type of female sex hormones, can in some cases be involved in the growth of breast cancer.

Fulvestrant EVER Pharma is used either:
- alone, to treat postmenopausal women with a type of breast cancer called estrogen receptor positive breast cancer that is locally advanced or has spread to other parts of the body (metastatic), or

- in combination with palbociclib to treat women with a type of breast cancer called hormone receptor-positive, human epidermal growth factor receptor 2-negative breast cancer, that is locally advanced or has spread to other parts of the body (metastatic). Women who have not reached menopause will also be treated with a medicine called a luteinizing hormone releasing hormone (LHRH) agonist.

When Fulvestrant EVER Pharma is given in combination with palbociclib, it is important that you also read the package leaflet for palbociclib. If you have any questions about palbociclib, please ask your doctor.

2. What you need to know before you use Fulvestrant EVER Pharma

Do not use Fulvestrant EVER Pharma**:**
- if you are allergic to fulvestrant or to any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or breast-feeding
- if you have severe liver problems

Warnings and precautions
Talk to your doctor or pharmacist before using Fulvestrant EVER Pharma if any of these apply to you:
- kidney or liver problems
- low numbers of platelets (which help blood clotting) or bleeding disorders
- previous problems with blood clots
- osteoporosis (loss of bone density)
- alcoholism

Children and adolescents
Fulvestrant EVER Pharma is not indicated in children and adolescents under 18 years.

Other medicines and Fulvestrant EVER Pharma
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, you should tell your doctor if you are using anticoagulants (medicines to prevent blood clots).

Pregnancy and breast-feeding
You must not use Fulvestrant EVER Pharma if you are pregnant. If you can become pregnant, you should use effective contraception while you are being treated with Fulvestrant EVER Pharma and for 2 years after your last dose.

You must not breast-feed while on treatment with Fulvestrant EVER Pharma.

Driving and using machines
Fulvestrant EVER Pharma is not expected to affect your ability to drive or use machines. However, if you feel tired after treatment do not drive or use machines.

Fulvestrant EVER Pharma contains ethanol
Fulvestrant EVER Pharma contains up to 500 mg of alcohol (ethanol) per syringe, which is equivalent to 10 vol %. The amount in each syringe of this medicine is equivalent to less than 10 ml beer or 4 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

To be taken into account in high-risk groups such as patients with liver disease or epilepsy.

Fulvestrant EVER Pharma contains benzyl alcohol
Fulvestrant EVER Pharma contains 500 mg benzyl alcohol in each syringe which is 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 EVER Pharma contains benzyl benzoate
Fulvestrant EVER Pharma contains 750 mg benzyl benzoate in each syringe which is equivalent to 150 mg/ml.

3. How to use Fulvestrant EVER Pharma

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Your doctor will give you Fulvestrant EVER Pharma as a slow intramuscular injection, one into each of your buttocks.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may need immediate medical treatment if you experience any of the following side effects:

- Allergic (hypersensitivity) reactions, including swelling of the face, lips, tongue and/or throat that may be signs of anaphylactic reactions
- Thromboembolism (increased risk of blood clots)*
- Inflammation of the liver (hepatitis)
- Liver failure

Tell your doctor or pharmacist, if you notice any of the following side effects:

Very common side effects (may affect more than 1 in 10 people)
- Injection site reactions, such as pain and/or inflammation
- Abnormal levels of liver enzymes (in blood tests) *
- Nausea (feeling sick)
- Weakness, tiredness*
- Joint and musculoskeletal pain
- Hot flushes
- Skin rash
- Allergic (hypersensitivity) reactions, including swelling of the face, lips, tongue and/or throat

All other side effects:

Common side effects (may affect up to 1 in 10 people)
- Headache
- Vomiting, diarrhoea, or loss of appetite*
- Urinary tract infections
- Back pain*
- Increase of bilirubin (bile pigment produced by the liver)
- Thromboembolism (increased risk of blood clots) *
- Decreased levels of platelets (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)

Uncommon side effects (may affect up to 1 in 100 people)
- Thick, whitish vaginal discharge and candidiasis (infection)
- Bruising and bleeding at the site of injection
- Increase of gamma-GT, a liver enzyme seen in a blood test
- Inflammation of the liver (hepatitis)
- Liver failure
- Numbness, tingling and pain
- Anaphylactic reactions

* Includes side effects for which the exact role of Fulvestrant EVER Pharma cannot be assessed due to the underlying disease.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Website: www.hpra.ieBy reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fulvestrant EVER Pharma

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or syringe labels after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Your healthcare professional will be responsible for the correct storage, use and disposal of Fulvestrant EVER Pharma.

This medicine may pose a risk to the aquatic environment.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fulvestrant EVER Pharma contains
- The active substance is fulvestrant. Each pre-filled syringe (5 ml) contains 250 mg fulvestrant. Each ml contains 50 mg fulvestrant.
- The other ingredients (excipients) are ethanol (96%), benzyl alcohol, benzyl benzoate, virgin castor oil.
  - Each pre-filled syringe contains 10 vol % ethanol (alcohol), i.e. up to 500 mg ethanol.
  - Each pre-filled syringe contains 500 mg benzyl alcohol which is equivalent to 100 mg/ml.

- Each pre-filled syringe contains 750 mg benzyl benzoate which is equivalent to 150 mg/ml.

What Fulvestrant EVER Pharma looks like and contents of the pack
Fulvestrant EVER Pharma is a clear, colourless to yellow, viscous solution, practically free from particles, in a pre-filled type I glass syringe fitted with bromobutyl rubber stopper, plunger rod and backstop, fitted with a tamper-evident closure, containing 5 ml solution for injection. Two syringes must be administered to receive the 500 mg recommended monthly dose.

Fulvestrant EVER Pharma has 2 pack presentations, either a pack containing 1 glass pre-filled syringe or a pack containing 2 glass pre-filled syringes. 21G x 1½ inch safety needles (BD SafetyGlide™) for connection to each barrel are also provided.
Multipacks containing 4 (2 packs of 2) or 6 (3 packs of 2) pre-filled syringes (5 ml each)
Not all pack sizes may be marketed.

Marketing Authorisation Holder
EVER Valinject GmbH
Oberburgau 3
4866 Unterach am Attersee
Austria

Manufacturer
EVER Pharma Jena GmbH
Otto-Schott-Straße 15
07745 Jena
Germany

This leaflet was last revised in July 2021

The following information is intended for healthcare professionals only:

Fulvestrant EVER Pharma 500 mg (2 x 250 mg/5 ml solution for injection in pre-filled syringe) should be administered using two pre-filled syringes, see section 3.

BD SafetyGlide is a trademark of Becton Dickinson and Company and is CE-marked: CE 0050.

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 EVER Pharma at the dorsogluteal injection site

Warning - Do not autoclave safety needle (BD SafetyGlide™ Shielding Hypodermic Needle) before use. Hands must remain behind the needle at all times during use and disposal.

For each of the one or two syringes:

- Carefully remove the needle and syringe from the packaging and check that it is not damaged.

- Peeling open the safety needle (BD SafetyGlide) outer packaging.

- Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.

- Remove the protective cap from the tip of the syringe barrel. To maintain sterility do not touch the syringe tip.

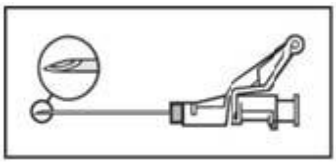
- Attach the safety needle to the Luer-Lock.

- 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 (gluteal area). 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.

<u>Disposal</u>
Pre-filled syringes are for single use **only**.

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