Package leaflet: Information for the user

<product name> 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <product name> is and what it is used for

<product name> 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.

<product name> 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 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 <product name>

Do not use <product name>
- 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, pharmacist or nurse before using <product name> 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
<product name> is not indicated in children and adolescents under 18 years.

Other medicines and <product name>
Tell your doctor or pharmacist if you are taking or 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, breast-feeding and fertility

Pregnancy
You must not use <product name> if you are pregnant. If you can become pregnant, you should use effective contraception while being treated with <product name> and for 2 years after your last dose.

Breast-feeding
You must not breast-feed while on treatment with <product name>.

Driving and using machines
<product name> 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.

<product name> contains 12.4 vol % ethanol (alcohol), i.e. up to 1000 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.

<product name> contains 500 mg benzyl alcohol in each 5 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")."

<product name> contains 750 mg benzyl benzoate in each 5 ml.

3. How to use <product name>

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 or nurse will give you <product name> 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, pharmacist or nurse.

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, pharmacist, or nurse 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 cannot be assessed due to the underlying disease.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <product name>

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

Store and transport in a refrigerator (2°C - 8°C).
Store the pre-filled syringe in the original package, in order to protect from light.

Temperature excursions outside 2°C - 8°C should be limited. This includes avoiding storage at temperatures exceeding 30°C, and not exceeding a 28-day period where the average storage temperature for the product is below 25°C (but above 2°C - 8°C). After temperature excursions, the product should be returned immediately to the recommended storage conditions (store and transport in a refrigerator 2°C - 8°C). Temperature excursions have a cumulative effect on the product quality and the 28-day time period must not be exceeded over the duration of the 48 months shelf life of <product name>. Exposure to temperatures below 2°C will not damage the product providing it is not stored below -20°C.

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

Your health care professional will be responsible for the correct storage, use and disposal of <product name> 250 mg solution for injection in pre-filled syringe.

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 <product name> contains
- The active substance is fulvestrant. Each pre-filled syringe (5 ml) contains 250 mg fulvestrant. Each ml of the solution contains 50 mg fulvestrant.
- The other ingredients are ethanol (96 per cent), benzyl alcohol, benzyl benzoate and castor oil, refined.

What <product name> looks like and contents of the pack
<product name> 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.

<product name> has two pack presentations:
- Carton box with a blister with one pre-filled syringe, one hypodermic sterile needle (BD SafetyGlide) and one leaflet.
Or
- Carton box with two blisters with one pre-filled syringe each, two hypodermic sterile needles (BD SafetyGlide) and one leaflet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

To be completed nationaly

This medicinal product is authorised in the Member States of the EEA under the following names:

To be completed nationaly

This leaflet was last revised in October 2020.

The following information is intended for healthcare professionals only:

<product name> should be administered using two pre-filled syringes, see section 3.

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 <product name> at the dorsogluteal injection site.

Warnings: 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 two syringes:

- Remove glass syringe barrel from blister and check that it is not damaged.
- Peel open the safety needle (SafetyGlide) outer packaging.
- Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.
- Hold the syringe upright.
- With the other hand, take hold of the protective cap and carefully twist the cap and remove. To maintain sterility do not touch the syringe tip (see Figure 1).

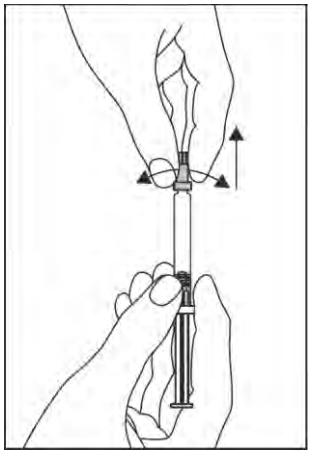

Figure 1

- Attach the safety needle to the Luer-Lock connector and twist until firmly seated (see Figure 2).

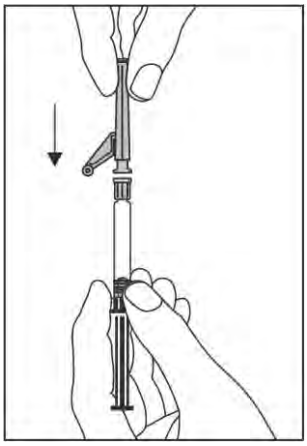

Figure 2

- Check that the needle is locked to the Luer-Lock connector before moving out of the vertical plane.
- Pull shield straight off needle to avoid damaging needle point.
- Transport pre-filled syringe to point of administration.
- Remove needle sheath.
- 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 3).

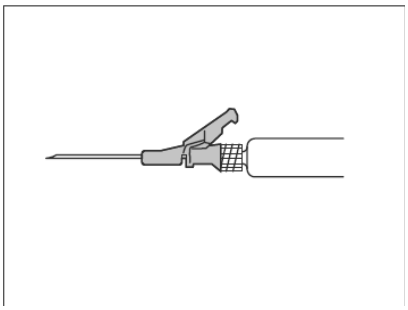

Figure 3

- After injection, immediately apply a single-finger stroke to the activation assisted lever arm to activate the shielding mechanism (see Figure 4).
  NOTE: Activate away from self and others. Listen for click and visually confirm needle tip is fully covered.

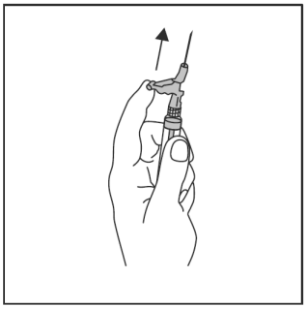

Figure 4

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.