Package leaflet: Information for the user

Fulvestrant 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** Fulvestrant **is and what it is used for**

Fulvestrant 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 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 Fulvestrant

Do not use Fulvestrant:
- if you are allergic to fulvestrant or 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 Fulvestrant 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 is not indicated in children and adolescents under 18 years.

Other medicines and Fulvestrant
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 if you are pregnant. If you can become pregnant, you should use effective contraception while being treated with Fulvestrant.

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

Driving and using machines
Fulvestrant 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 contains 10% w/v ethanol (alcohol), i.e. up to 500 mg per dose, equivalent to 10 ml beer or 4 ml wine per dose.
Harmful for those suffering from alcoholism.
To be taken into account in high-risk groups such as patients with liver disease, or epilepsy.

Fulvestrant contains 500 mg benzyl alcohol per injection, 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 contains 750 mg benzyl benzoate per injection, equivalent to 150 mg/ml.

3. How to use Fulvestrant

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 Fulvestrant 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)
- Anaphylactic reactions
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- 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

* 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 (see contact details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Fulvestrant

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.

Store and transport refrigerated (2°C-8°C).

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 refrigerated (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 2 years shelf life of Fulvestrant. Exposure to temperatures below 2°C will not damage the product providing it is not stored below –20°C.

Keep the pre-filled syringe in the original package, in order to protect from light.

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

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 contains
- The active substance is fulvestrant. Each pre-filled syringe (5 ml) contains 250 mg fulvestrant.
- The other ingredients (excipients) are ethanol (96 per cent), benzyl alcohol, benzyl benzoate and castor oil, refined.

What Fulvestrant looks like and contents of the pack
Fulvestrant is a clear, colourless to yellow, viscous solution.
Fulvestrant is contained in a clear type I glass pre-filled syringe with plunger stopper and plunger rod, fitted with the tamper evident closure containing 250 mg fulvestrant in 5 ml solution.
A safety needle (BD SafetyGlide®) for connection to the barrel is also provided.

Fulvestrant is provided in a pack of two single-use pre-filled syringes.

Marketing Authorisation Holder and Manufacturer

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola, PLA 3000, Malta

This leaflet was last revised in July 2020.

The following information is intended for healthcare professionals only:

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

Instructions for administration

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®.

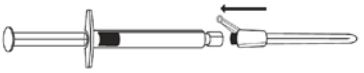
For each of the two syringes:

- Carefully remove glass syringe barrel from tray and check that it is not damaged.
- Twist the plastic cover of the tamper evident closure on the syringe Luer to remove the cover with the attached rubber tip cap (see Figure 1).

Figure 1

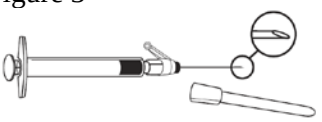
- Peel open the safety needle (BD SafetyGlide) outer packaging. Attach the safety needle to the Luer connector (see Figure 2).
- Twist to lock the needle to the Luer connector. Twist until firmly seated.
- Pull shield straight off needle to avoid damaging needle point.
- Transport filled syringe to point of administration.
- Remove needle sheath.
- Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.
- Expel excess gas from the syringe.

Figure 2



- Administer intramuscularly slowly (1-2 minutes/injection) into the buttock. For user convenience, the needle bevel- up position is oriented to the lever arm (see Figure 3).

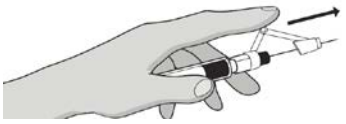
Figure 3



- After injection, immediately activate safety mechanism by pushing the Luer arm forward until needle tip is completely covered (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 product or waste material should be disposed of in accordance with local requirements.