Package leaflet: Information for the user

Fulvestrant Seacross 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 Seacross is and what it is used for

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

Fulvestrant Seacross is used either:
- alone, to treat postmenopausal women with a type of breast cancer called oestrogen 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 Seacross 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 Seacross

Do not use Fulvestrant Seacross:
- 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 or nurse before using Fulvestrant Seacross 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 Seacross is not indicated in children and adolescents under 18 years.

Other medicines and Fulvestrant Seacross
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 Seacross if you are pregnant. If you can become pregnant, you should use effective contraception while you are being treated with Fulvestrant Seacross and for 2 years after your last dose.

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

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

Fulvestrant Seacross 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 are pregnant or breast-feeding or 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 Seacross contains 750 mg benzyl benzoate per injection, equivalent to 150 mg/ml.

3. How to use Fulvestrant Seacross

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 Seacross 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 Seacross 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 Yellow Card Scheme website: http://www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fulvestrant Seacross

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 medicine does not require any special storage conditions.

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

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 Seacross 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 Seacross looks like and contents of the pack
Fulvestrant Seacross is a clear, colourless to yellow, viscous solution in a pre-filled syringe with ETFE coated bromobutyl rubber plunger stopper, containing 5 ml solution for injection. Two syringes must be administered to receive the 500 mg recommended monthly dose.

Fulvestrant Seacross has a pack containing 2 glass pre-filled syringes. Safety needles (Terumo SurGuard) for connection to each barrel are also provided.

Marketing Authorisation Holder
Seacross Pharmaceuticals Limited
Bedford Business Centre
61-63 St Peters Street
Bedford, MK40 2PR
United Kingdom

Manufacturer
Seacross Pharmaceuticals Limited
Stanmore Business & Innovation Centre
Stanmore Place
Howard Road
Stanmore, HA7 1BT
United Kingdom

This leaflet was last revised in 09/2024

The following information is intended for healthcare professionals only:

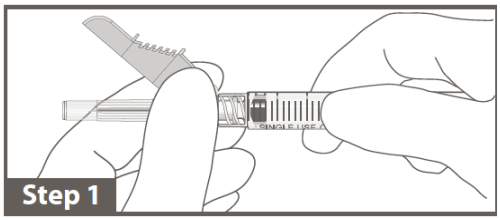
Fulvestrant Seacross 500 mg (2 x 250 mg/5 ml solution for injection) should be administered using two pre-filled syringes, see section 3.

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

For each of the two syringes:

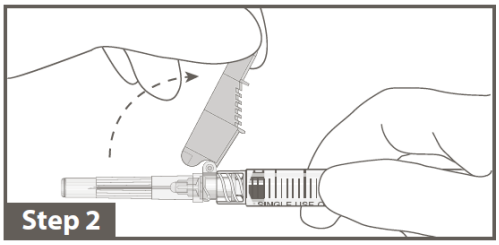
- Carefully remove the needle and syringe from the packaging.
- Remove the protective cap from the tip of the syringe barrel.
- Tighten the syringe to the needle using aseptic technique. Grip the base of the needle, not the sheath, and turn the syringe clockwise (see Figure 1).

Figure 1



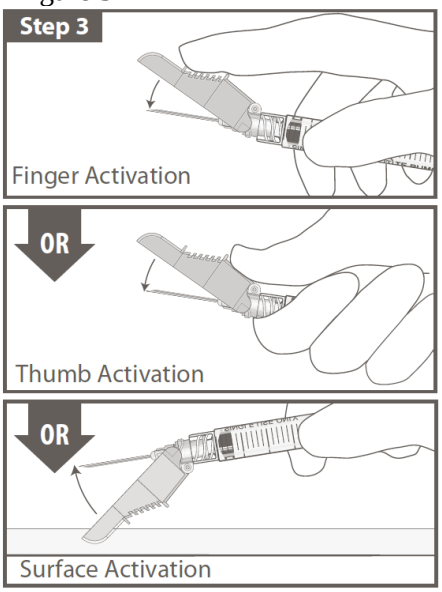
- Move the safety shield away from the needle and toward the syringe barrel to the angle shown. Then remove the needle cap (see Figure 2).
- While holding the syringe with the needle pointing upward, gently push in the plunger until the medicine is up to the top of the syringe. There should be no air within the barrel.
- Administer intramuscularly slowly (1-2 minutes/injection) into the buttock.

Figure 2



- After completing the injection, remove the needle from the skin and use a one-handed technique to activate the safety mechanism using any of the three methods (see Figure 3):
  - Finger activation
  - Thumb activation
  - Surface activation

Figure 3



Activation is verified by an audible and/or tactile "click", and can be visually confirmed. If uncertain that the safety shield is fully engaged, repeat this step.

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.