Package leaflet: Information for the user

Fulvestrant Rowex 250mg/5ml 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 Rowex is and what it is used for
2. What you need to know before you use Fulvestrant Rowex
3. How to use Fulvestrant Rowex
4. Possible side effects
5. How to store Fulvestrant Rowex
6. Contents of the pack and other information

1. What Fulvestrant Rowex is and what it is used for

Fulvestrant Rowex 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 Rowex 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 Rowex 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 Rowex

Do not use Fulvestrant Rowex:
- 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 Fulvestrant Rowex 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 Rowex is not indicated in children and adolescents under 18 years.

Other medicines and Fulvestrant Rowex
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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
You must not use Fulvestrant Rowex if you are pregnant. If you can become pregnant, you should use effective contraception while being treated with Fulvestrant Rowex and for 2 years after your last dose.

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

Driving and using machines
Fulvestrant Rowex 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 Rowex contains ethanol, benzyl alcohol and benzyl benzoate
This medicine contains 1000 mg of alcohol (ethanol 96%) per given dose, which is equivalent to 100 mg/ml (10% w/v). The amount per given dose of this medicine is equivalent to less than 24 ml beer or 10 ml wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

This medicinal product contains 1000 mg benzyl alcohol per given dose, which is equivalent to 100 mg/ml.
Benzyl alcohol may cause allergic reactions.
Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children.
Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.
Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

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").
This medicine contains 1500 mg benzyl benzoate per given dose, which is equivalent to 150 mg/ml. Benzyl benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to use Fulvestrant Rowex

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 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 Rowex 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 Rowex cannot be assessed due to the underlying disease.

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fulvestrant Rowex

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 label after the abbreviation 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.

Do not use this medicine if you notice that the device or content has deteriorated in any way, such as damage to the syringe, cloudy solution, floating particles, or change in the colour of the solution.

Do not throw away 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 Rowex contains

- The active substance is fulvestrant.
  Each pre-filled syringe contains 250 mg fulvestrant in 5 ml solution (50 mg/ml).
- The other excipients are ethanol (96 per cent), benzyl alcohol, benzyl benzoate and castor oil.

What Fulvestrant Rowex looks like and contents of the pack
Fulvestrant Rowex is a clear, colourless to yellow, viscous solution for injection in a pre-filled syringe.

Fulvestrant Rowex is provided in one or two single-use pre-filled syringes. Additionally a sterile needle is provided.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Fareva Unterach GmbH, Mondseestraße 11, 4866 Unterach , Austria.

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

Austria	Fulvestrant Sandoz 50mg/ml –Injektionslösung in einer Fertigspritze
Belgium	Fulvestrant Sandoz 250 mg oplossing voor injectiein een voorgevulde spuit
Bulgaria	Fulvestrant Sandoz 250 mg/5 ml Solution for injection in pre-filled syringe
Czech Republic	Fulvestrant Sandoz
Germany	Fulvestrant 1A Pharma 250 mg Injektionslősung in einer fertigspritze
Denmark	Fulvestrant Sandoz
Estonia	Fulvestrant Sandoz
Spain	Afultrant 250 mg solución inyectable en jeringa precargada EFG
Finland	Fulvestrant Sandoz 250 mg injektioneste, liuos esitäytetyssä ruisku
France	FULVESTRANT SANDOZ 250 mg, solution injectable en seringue pré-remplie
Croatia	Fulvestrant Sandoz 250 mg otopina za injekciju u napunjenoj štrcaljki
Hungary	Fulvestrant Sandoz 250 mg oldatos injekció előretöltött fecskendőben
Ireland	Fulvestrant Rowex 250 mg/5 ml Solution for injection in pre-filled syringe
Iceland	Fulvestrant Sandoz 250 mg stungulyf, lausn í áfylltri sprautu
Italy	Fulvestrant Sandoz
Lithuania	Fulvestrant Sandoz 250 mg/ml injekcinis tirpalas užpildytame švirkšte
Netherlands	Fulvestrant Sandoz 50 mg/ml, oplossing voor injectie in voorgevulde injectiespuit

Norway	Fulvestrant Sandoz 250 mg injeksjonsvæske, oppløsning i ferdigfylt sprøyte
Poland	Fulvestrant Sandoz
Portugal	Fulvestrant Sandoz
Romania	Fulvestrant Sandoz 250 mg soluţie injectabilă in seringa preumpluta
Sweden	Fulvestrant Sandoz 250 mg injektionsvätska, lösning i förfylld spruta
Slovenia	Fulvestrant Lek 250 mg raztopina za injiciranje v napolnjeni injekcijski brizgi
Slovakia	Fulvestrant Sandoz 250mg
United Kingdom	Fulvestrant 250 mg, Solution for Injection in pre-filled syringe

This leaflet was last revised in 09/2021.

The following information is intended for healthcare professionals only:

Fulvestrant Rowex 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:

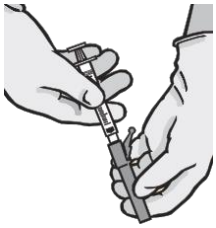
Warning - Do not autoclave safety needle before use. Hands must remain behind the needle at all times during use and disposal.

Syringes are supplied with safety needle BD SafetyGlide® or Terumo SurGuard®.

Instructions for safety needle BD SafetyGlide®

For each of the two syringes:

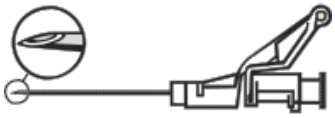
- Carefully remove the needle and syringe from the packaging.
- Remove the protective cap from the tip of the syringe barrel
- Peel open the safety needle (BD SafetyGlide) outer packaging. Attach the safety needle to the Luer-Lock
- Twist to lock the needle to the Luer connector. Twist until firmly seated.
- 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

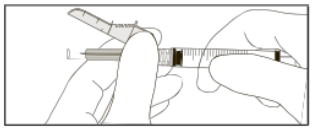
NOTE: Activate away from self and others. Listen for click and visually confirm needle tip is fully covered.

<u>Instructions for safety needle Terumo SurGuard®</u>

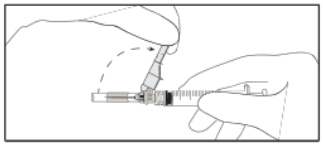
For each of the two syringes:

- 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.



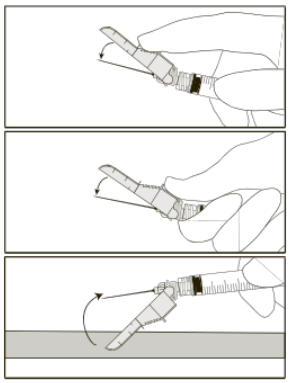
- Move the safety shield away from the needle and toward the syringe barrel to the angle shown. Then remove the needle cap.



- 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.

- 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:
    - Finger activation
    - Thumb activation
    - Surface activation



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**.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.