TEVA
HOSPITALS

Package leaflet: Information for the user

FULVESTRANT 250 mg SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

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 Solution for Injection in Pre-filled Syringe 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)
- are pregnant or breast-feeding (see section "Pregnancy and breast-feeding")
- 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 (see section "Fulvestrant contains ethanol 96% (alcohol)").

The efficacy and safety of fulvestrant (either as monotherapy or in combination with palbociclib) have not been studied in patients with critical visceral disease.

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 you are being treated with Fulvestrant and for 2 years after your last dose.

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 ethanol 96% (alcohol)
This medicine contains 474 mg of alcohol (ethanol) in each pre-filled syringe of 5 ml which is eqivalent to 94.8 mg/ml. The amount in one dose of 10 ml 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.

Fulvestrant contains benzyl alcohol
This medicine contains 500 mg benzyl alcohol in each pre-filled syringe of 5 ml which is equivalent to 100 mg per 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 benzyl benzoate
This medicine contains 750 mg benzyl benzoate in each pre-filled syringe of 5 ml which is equivalent to 150 mg per 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:

Side effects reported in patients treated with Fulvestrant monotherapy:

Very common: 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: may affect up to 1 in 10 people
- headache
- vomiting (being sick), 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: 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.

Side effects reported in patients treated with Fulvestrant in combination therapy with palbociclib:

Very common: may affect more than 1 in 10 people
- neutrophil count decrease (neutropenia)
- white blood cell count decrease (leukopenia)
- infections
- tiredness
- nausea (feeling sick)
- reduction in red blood cells (anaemia)
- inflammation or ulceration of the mouth
- diarrhoea
- decreased levels of platelets (thrombocytopenia)
- vomiting (being sick)
- hair loss
- rash
- loss of appetite
- fever.

Common: may affect up to 1 in 10 people
- feeling weak
- increased level of liver enzymes
- loss of taste
- nosebleed
- excessively wet eye
- dry skin
- blurred vision
- dry eye.

Uncommon: may affect up to 1 in 100 people
- fever with other signs of infection (febrile neutropenia).

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 Yellow Card Scheme Website: 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

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.

Do not use this medicine if you notice any particles or discolouration prior to administration.

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 25 °C and not exceeding a 4 months 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 4 months time period must not be exceeded over the duration of the 2-year 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 contains 250 mg fulvestrant. Each ml of solution contains 50 mg of fulvestrant.
- The other ingredients (excipients) are ethanol (96%), 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 in a pre-filled syringe fitted with a Luer-Lock connector, containing 5 ml solution for injection. Two syringes must be administered to receive the 500 mg recommended monthly dose.

Fulvestrant has 2 pack presentations:
- 1 pack containing 1 glass pre-filled syringe and 1 safety needle for connection to the barrel.
- 1 pack containing 2 glass pre-filled syringes and 2 safety needles for connection to each barrel are also provided.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer
Pliva Croatia Ltd., Prilaz baruna Filipovica 25, 10000 Zagreb, Croatia

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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
Administer the injection according to the local guidelines for performing large volume intramuscular injections.

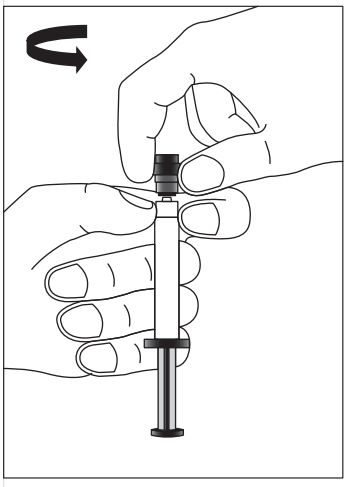
NOTE: Due to the proximity of the underlying sciatic nerve, caution should be taken if administering Fulvestrant at the dorsogluteal injections site (see section 4.4).

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:

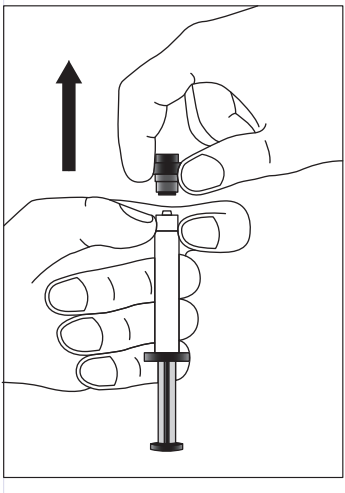
- Remove glass syringe barrel from tray and check that it is not damaged.
- Peel open the safety needle outer packaging.
- Parental solutions must be inspected visually for particulate matter and discolouration prior to administration.
- Hold the syringe upright on the ribbed part (C). With the other hand, take hold of the cap (A) and carefully twist the cap counter-clockwise until the cap disconnects for removal (see Figure 1).

Figure 1



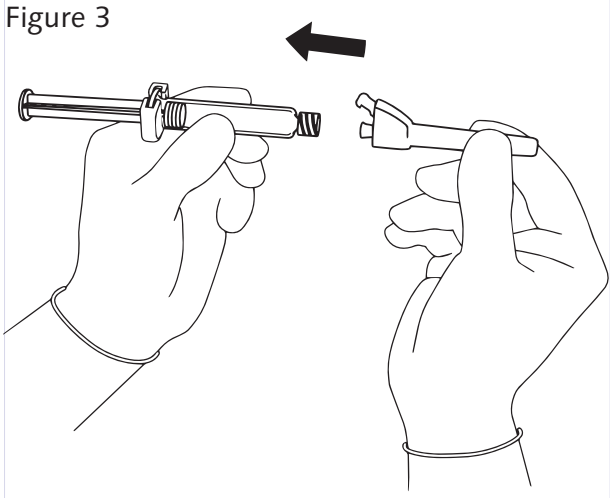
- Remove the cap (A) in a straight upward direction. To maintain sterility DO NOT TOUCH THE STERILE SYRINGE TIP (Luer-Lock) (B) (see Figure 2).

Figure 2



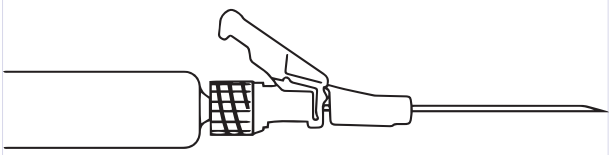
- Attach the safety needle to the Luer-Lock and twist until firmly seated (see Figure 3).
- Check that the needle is locked to the Luer connector.
- Transport filled syringe to point of administration.
- Pull shield straight off needle to avoid damaging needle point.

Figure 3



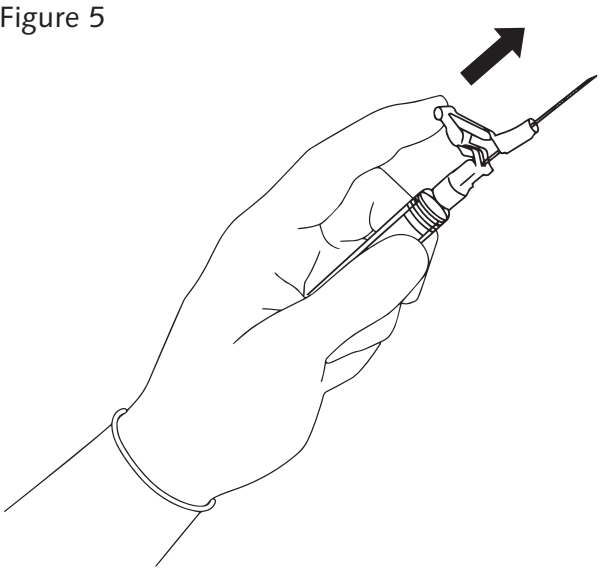
- Expel excess gas from the syringe.
- Administer intramuscularly slowly (1-2 minutes/injection) into the buttock (gluteal area). For user convenience, the needle bevel-up position is oriented to the lever arm (see Figure 4).

Figure 4



- After injection, immediately apply a single-finger stroke to the activation assisted lever arm to activate the needle shielding mechanism (see Figure 5). NOTE: Activate away from self and others. Listen for click and visually confirm needle tip is fully covered.

Figure 5



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.