

## 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**
2. **What you need to know before you use Fulvestrant**
3. **How to use Fulvestrant**
4. **Possible side effects**
5. **How to store Fulvestrant**
6. **Contents of the pack and other information**

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

Fulvestrant solution for injection 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 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 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 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, benzyl alcohol, benzyl benzoate.**

#### *Ethanol*

This medicine contains 500 mg alcohol (ethanol) in each pre-filled syringe. The amount in one dose (two pre-filled syringes) of this medicine is equivalent to 25 ml beer or 10 ml wine. The amount of alcohol in this medicine is not likely to have an effect in adults. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

#### *Benzyl alcohol*

This medicine contains 500 mg benzyl alcohol in each pre-filled syringe. 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”).

#### *Benzyl benzoate*

This medicine contains 750 mg benzyl benzoate in each pre-filled syringe.

## **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)
- 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:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie).

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 and pre-filled syringe label 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-year shelf life of fulvestrant. Exposure to temperatures below 2 °C will not damage the product providing it is not stored below -20 °C.

Store 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. Each ml contains 50 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 in a pre-filled syringe fitted with a tamper-evident closure, containing 5 ml solution for injection. Two syringes must be administered to receive the 500 mg recommended monthly dose.

Fulvestrant has 4 pack presentations: a pack containing 1 glass pre-filled syringe, a pack containing 2 glass pre-filled syringes, a pack containing 4 glass pre-filled syringes, and a pack containing 6 pre-filled syringes. Safety needles for connection to each barrel and a finger grip on each pre-filled syringe are also provided.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Reddy Holding GmbH  
Kobelweg 95  
86156 Augsburg  
Germany

### **Manufacturer**

betapharm Arzneimittel GmbH  
Kobelweg 95  
86156 Augsburg  
Germany

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Austria: Fulvestrant Reddy 250 mg Injektionslösung in einer Fertigspritze

Belgium, Netherland: Fulvestrant Reddy 250 mg oplossing voor injectie in een voorgevulde spuit  
Czech Republic, Denmark, Norway, Poland: Fulvestrant Reddy  
Germany: Fulvestrant beta 250 mg Injektionslösung in einer Fertigspritze  
Finland: Fulvestrant Reddy 250 mg injektioneste, liuos, esitäytetty ruisku  
Hungary: Fulvestrant Reddy 250 mg oldatos injekció előretöltött fecskendőben  
Ireland: Fulvestrant 250 mg solution for injection in pre-filled syringe  
Portugal: Fulvestrante Reddy 250 mg solução injetável em seringa pré-cheia  
Sweden: Fulvestrant Reddy 250 mg injektionsvätska, lösning i förfylld spruta  
Slovakia: Fulvestrant Reddy 250 mg injekčný roztok v naplnenej injekčnej striekačke

**This leaflet was last revised in**  
[to be completed nationally]

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**The following information is intended for healthcare professionals only:**

Fulvestrant 500 mg (2 x 250 mg injections) should be administered using two pre-filled syringes, see section 3.

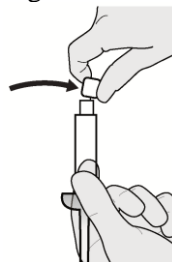
**Instructions for administration**

**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:

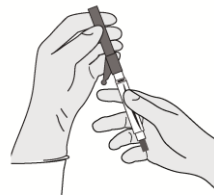
- Remove glass syringe barrel from blister tray and check that it is not damaged.
- Peel open the safety needle outer packaging.
- Parenteral solutions must be inspected visually for particulate matter and discolouration prior to administration.
- Hold the syringe upright and break the seal of the white plastic cover on the syringe Luer connector Luer-Lok to remove the cover with the attached rubber tip cap (see Figure 1).
- Remove the cap in a straight upward direction. To maintain sterility do not touch the syringe tip.

Figure 1



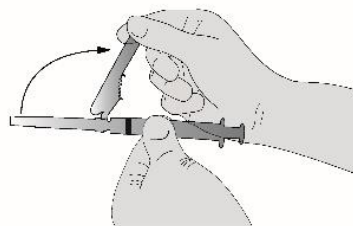
- Attach the safety needle to the Luer-Lok and twist until firmly seated (see Figure 2).
- Check that the needle is locked to the Luer connector before moving out of the vertical plane.

Figure 2



- Move the safety sheath away from the needle and toward the syringe barrel to the angle shown on Figure 3.
- Pull shield straight off needle to avoid damaging needle point.
- Transport filled syringe to point of administration.
- Remove needle sheath. Expel excess gas from the syringe.

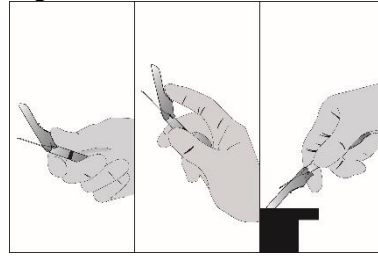
Figure 3



- 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).
- Use the finger grip if necessary.

- After injection, use a one-handed technique to activate the safety mechanism using any of the three methods illustrated here (Activation is verified by an audible and/or tactile “click” and can be visually confirmed.) (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.