

## **Package leaflet: Information for the User**

### **Faslodex 250 mg solution for injection**

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.

#### **What is in this leaflet:**

1. What Faslodex is and what it is used for.
2. What you need to know before you use Faslodex.
3. How to use Faslodex.
4. Possible side effects.
5. How to store Faslodex.
6. Contents of the pack and other information.

### **1. What Faslodex is and what it is used for**

Faslodex 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.

Faslodex is used to treat advanced or metastatic breast cancer in postmenopausal women.

### **2. What you need to know before you use Faslodex**

#### **Do not use Faslodex**

- if you are allergic to fulvestrant or to any of the other ingredients of this medicine (listed in section 6 ‘What Faslodex contains’)
- if you are pregnant or breast-feeding
- if you have severe liver problems.

#### **Warnings and precautions**

Tell your doctor 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**

Faslodex is not indicated in children and adolescents under 18 years.

#### **Other medicines and Faslodex**

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken 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 Faslodex if you are pregnant. If you can become pregnant, you should use effective contraception while being treated with Faslodex.

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

### **Driving and using machines**

Faslodex 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.

**Faslodex contains** 10 % w/v ethanol (alcohol), i.e. up to 1000 mg per dose, equivalent to 20 ml beer or 8 ml wine per dose.

Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

## **3. How to use Faslodex**

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 Faslodex as a slow intramuscular injection, one into each of your buttocks.

## **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
- 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.\*

**All other side effects:**

**Common side effects** (may affect up to 1 in 10 people)

- Headache.

- Hot flushes.
- Vomiting, diarrhoea, or loss of appetite.\*
- Rash.
- Urinary tract infections.
- Back pain.\*
- Increase of bilirubin (bile pigment produced by the liver).
- Thromboembolism (increased risk of blood clots).\*
- Allergic (hypersensitivity) reactions, including swelling of the face, lips, tongue and/or throat.

**Uncommon side effects** (may affect up to 1 in 100 people)

- Vaginal bleeding, thick, whitish 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.

\* Includes side effects for which the exact role of Faslodex cannot be assessed due to the underlying disease.

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet.

## 5. How to store Faslodex

Store and transport in a refrigerator (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 in a refrigerator 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 4-year shelf life of Faslodex. 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.

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 the abbreviation EXP. The expiry date refers to the last day of that month.

Your health care professional will be responsible for the correct storage, use and disposal of Faslodex.

## 6. Contents of the pack and other information

### What Faslodex 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.

### **What Faslodex looks like and contents of the pack**

Faslodex 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.

Faslodex has 2 pack presentations, either a pack containing 1 glass pre-filled syringe or a pack containing 2 glass pre-filled syringes. Safety needles (BD SafetyGlide™) for connection to each barrel are also provided.

Not all pack sizes may be marketed.

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**Other sources of information**

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.