

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

Fulvestrant

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

**In this leaflet:**

1. What Faslodex is and what it is used for
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**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. BEFORE YOU USE FASLODEX**

**Do not use Faslodex**

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

**Take special care with FASLODEX**

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

### **Using other medicines**

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

### **Important information about some of the ingredients of Faslodex**

This medicinal product 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 usual 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, Faslodex can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000

- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

#### Very common side effects

- Injection site reactions, such as pain and/or inflammation
- Abnormal levels of liver enzymes (in blood tests)
- Nausea (feeling sick)
- Weakness, tiredness

#### Common side effects

- Headache
- Hot flushes
- Vomiting, diarrhoea, or loss of appetite
- Rash
- Urinary tract infections
- Back pain
- Thromboembolism (Increased risk of blood clots)

- Allergic (hypersensitivity) reactions, including swelling of the face, lips, tongue and/or throat

**Uncommon side effects**

- Vaginal bleeding, thick, whitish discharge and candidiasis (infection)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

**5. HOW TO STORE FASLODEX**

Store in a refrigerator (2°C – 8°C).

Keep the pre-filled syringe in the original package, in order to protect from light.

Keep out of the reach and sight of children.

Do not use 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. FURTHER INFORMATION

### What Faslodex contains

- The active substance is fulvestrant. Each pre-filled syringe (5 ml) contains 250 mg fulvestrant.
- The other ingredients 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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