

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. See section 4.

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
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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:

- 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).
- 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 Faslodex 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.

- in combination with capivasertib to treat adult patients who have hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative breast cancer that is advanced or that has spread to other parts of the body with one or more abnormal “PIK3CA”, “AKT1”, or “PTEN” gene and whose cancer is not responding to other anti-hormonal based therapies. Your healthcare provider will test your cancer to see if it has at least one abnormal “PIK3CA”, “AKT1”, or “PTEN” gene to make sure that capivasertib is right for you. For women who have not reached menopause, your doctor will prescribe a medicine called LHRH agonist. For men, your healthcare provider may prescribe a LHRH agonist.

When Faslodex is given in combination with capivasertib, it is important that you also read the package leaflet for capivasertib. If you have any questions about capivasertib, please ask your doctor.

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)
- 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 Faslodex 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

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 Faslodex if you are pregnant. If you can become pregnant, you should use effective contraception while you are being treated with Faslodex and for 2 years after your last dose.

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 500 mg per injection, equivalent to 10 ml beer or 4 ml wine.

Harmful for those suffering from alcoholism.

To be taken into account in high-risk groups such as patients with liver disease, or epilepsy.

Faslodex contains 500 mg benzyl alcohol per injection, equivalent to 100 mg/ml.

Benzyl alcohol may cause allergic reactions.

Faslodex contains 750 mg benzyl benzoate per injection, equivalent to 150 mg/ml.

3. How to use Faslodex

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 Faslodex 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 Faslodex 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 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 Faslodex

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.

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.

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

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 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 refined.

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.

Marketing Authorisation Holder

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Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

| Product name | Reference number |
|--|-------------------------|
| Faslodex 250 mg solution for injection | 17901/0323 |

This is a service provided by the Royal National Institute of the Blind.