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EPAR summary for the public

Faslodex

fulvestrant

This is a summary of the European public assessment report (EPAR) for Faslodex. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Faslodex.

For practical information about using Faslodex, patients should read the package leaflet or contact their doctor or pharmacist.

What is Faslodex and what is it used for?

Faslodex is an anti-oestrogen medicine used to treat advanced or metastatic breast cancer (cancer that has spread to other parts of the body) in the following patients:

- postmenopausal women with a type of breast cancer known as 'oestrogen-receptor positive cancer' who have not previously had hormonal treatment, or whose cancer had come back after treatment with another anti-oestrogen;
- women with a type of breast cancer known as 'HR-positive, HER-2 negative cancer' who have previously had hormonal treatment. In women with this type of breast cancer, Faslodex is used in combination with palbociclib (another cancer medicine).

Faslodex contains the active substance fulvestrant.

How is Faslodex used?

Faslodex is available as a solution for injection in prefilled syringes (250 mg). The recommended dose is 500 mg given once a month, with an additional 500-mg dose two weeks after the first dose. The dose is given as two injections, each given into the muscle of one buttock over one to two minutes.

Faslodex can only be obtained with a prescription.

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How does Faslodex work?

Most types of breast cancer are stimulated to grow when the hormone oestrogen attaches to targets (receptors) on cancer cells. The active substance in Faslodex, fulvestrant, is an anti-oestrogen. It blocks the receptors for oestrogen on cells and causes the number of oestrogen receptors to fall. As a result, the cancer cells are not stimulated to grow by oestrogen and this slows down the growth of the tumour.

What benefits of Faslodex have been shown in studies?

Five main studies showed that Faslodex is effective at prolonging the length of time patients live without their disease getting worse.

Two of these studies in 851 women showed that Faslodex was as effective as another medicine, anastrozole: women receiving Faslodex lived for an average of 5.4 months without their disease getting worse, compared with 4.1 months for those taking anastrozole.

A third study in 736 women showed that the higher dose of 500 mg of Faslodex was more effective than 250 mg: women receiving the higher dose lived for an average of 6.5 months without their disease getting worse, compared with 5.5 months in those receiving the lower dose.

The fourth study, in 462 women with advanced or metastatic breast cancer who had not been treated with hormonal therapy, showed that women treated with Faslodex (500 mg once a month) lived for an average of 16.6 months without their disease getting worse, compared with 13.8 months for women given anastrozole.

Finally, a study investigating the use of Faslodex in combination with palbociclib in 521 women with (HR)-positive (HER2)-negative advanced or metastatic breast cancer showed that women treated with Faslodex plus palbociclib lived for an average of 9.2 months without their disease getting worse, compared with 3.8 months for women given Faslodex on its own.

What are the risks associated with Faslodex?

When Faslodex is used on its own, the most common side effects (seen in more than 1 patient in 10) are injection-site reactions (such as pain or inflammation), weakness, nausea (feeling sick) and increased liver enzyme levels in the blood (a sign of liver problems). When used in combination with palbociclib, the most common side effects with Faslodex (seen in more than 2 patients in 10) are low levels of white and red blood cells, low blood platelet counts, infections, tiredness, nausea, stomatitis (inflammation of the lining of the mouth) and diarrhoea. The most common serious side effects were low levels of white and red blood cells, low levels of blood platelets, infections, increased liver enzyme levels and tiredness.

Faslodex must not be used in women who are pregnant or breast-feeding, or in patients who have severe liver disease. For the full list of all side effects and restrictions with Faslodex, see the package leaflet.

Why is Faslodex approved?

Studies showed that Faslodex, an anti-oestrogen medicine, is effective at prolonging the time patients with oestrogen-receptor positive breast cancer can live without their disease getting worse. In addition, the medicine is effective in combination with palbociclib in patients with HR-positive, HER-2 negative breast cancer. The European Medicines Agency concluded that the benefits seen in studies with Faslodex are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Faslodex?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Faslodex have been included in the summary of product characteristics and the package leaflet.

Other information about Faslodex

The European Commission granted a marketing authorisation valid throughout the European Union for Faslodex on 10 March 2004.

The full EPAR for Faslodex can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Faslodex, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2018.