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EPAR summary for the public

Fulvestrant Mylan

fulvestrant

This is a summary of the European public assessment report (EPAR) for Fulvestrant Mylan. 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 Fulvestrant Mylan.

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

What is Fulvestrant Mylan and what is it used for?

Fulvestrant Mylan is an anti-oestrogen medicine used to treat advanced or metastatic breast cancer (cancer that has spread to other parts of the body) in 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.

Fulvestrant Mylan contains the active substance fulvestrant.

Fulvestrant Mylan is a 'generic medicine'. This means that Fulvestrant Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Faslodex. For more information on generic medicines, see the question-and-answer document here.

How is Fulvestrant Mylan used?

Fulvestrant Mylan can only be obtained with a prescription and 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 given 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.

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How does Fulvestrant Mylan 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 Fulvestrant Mylan, 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.

How has Fulvestrant Mylan been studied?

Studies on the benefits and risks of the active substance in the approved use have already been carried out with the reference medicine, Faslodex, and do not need to be repeated for Fulvestrant Mylan.

As for every medicine, the company provided studies on the quality of Fulvestrant Mylan. There was no need for 'bioequivalence' studies to investigate whether Fulvestrant Mylan is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Fulvestrant Mylan is the same as the reference medicine and when given by injection into the muscle, the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Fulvestrant Mylan?

Because Fulvestrant Mylan is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Fulvestrant Mylan approved?

The European Medicines Agency concluded that, in accordance with EU requirements, Fulvestrant Mylan has been shown to be comparable to Faslodex. Therefore, the Agency's view was that, as for Faslodex, the benefit outweighs the identified risk. The Agency recommended that Fulvestrant Mylan be approved for use in the EU.

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

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

Other information about Fulvestrant Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Fulvestrant Mylan on 8 January 2018.

The full EPAR for Fulvestrant Mylan 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 Fulvestrant Mylan, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 01-2018.