9 November 2017
EMA/CHMP/734315/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fulvestrant Mylan

fulvestrant

On 9 November 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fulvestrant Mylan, intended for the treatment of locally advanced or metastatic breast cancer. The applicant for this medicinal product is Mylan S.A.S.

Fulvestrant Mylan will be available as a 250-mg solution for injection. The active substance of Fulvestrant Mylan is fulvestrant, an anti-oestrogen which attaches to the receptors for oestrogen on the surface of cells, thereby blocking the effects of the hormone and causing the number of oestrogen receptors to fall (ATC code: L02BA03). As a result, the tumour cells are not stimulated to grow by oestrogen and the growth of the tumour is reduced.

Fulvestrant Mylan is a generic of Faslodex, which has been authorised in the EU since 10 March 2004. Studies have demonstrated the satisfactory quality of Fulvestrant Mylan. Since Fulvestrant Mylan is of the same type of solution, contains the same concentration of the active substance and has the same excipients in similar amounts as the medicinal product currently approved, a bioequivalence study versus the reference product Faslodex was not required. A question and answer document on generic medicines can be found here.

The full indication is:

"Fulvestrant is indicated for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women:

- not previously treated with endocrine therapy, or
- with disease relapse on or after adjuvant antiestrogenanti-estrogen therapy, or disease progression on antiestrogen therapy."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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