EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2015
EMA/CHMP/238545/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion [1] (initial authorisation)

Duloxetine Mylan

Duloxetine

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Duloxetine Mylan, intended for the treatment of major depressive disorder, diabetic peripheral neuropathic pain, and generalised anxiety disorder in adults. The applicant for this medicinal product is Generics (UK) Limited.

Duloxetine Mylan will be available as 30 mg and 60 mg gastro-resistant capsules. The active substance of Duloxetine Mylan is duloxetine, a combined serotonin (5-HT) and noradrenaline (NA) reuptake inhibitor. It weakly inhibits dopamine re-uptake with no significant affinity for histaminergic, dopaminergic, cholinergic and adrenergic receptors (ATC code: N06AX21).

Duloxetine Mylan is a generic of Cymbalta, which has been authorised in the EU since 17 December 2004. Studies have demonstrated the satisfactory quality of Duloxetine Mylan, and its bioequivalence to the reference product. A question and answer document on generic medicines can be found here.

The full indication is: “Treatment of major depressive disorder. Treatment of diabetic peripheral neuropathic pain. Treatment of generalised anxiety disorder. Duloxetine Mylan is indicated in adults. For further information see section 5.1.".

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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