26 June 2015
EMA/CHMP/431635/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Duloxetine Zentiva

duloxetine

On 25 June 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 Zentiva, intended for the treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder. The applicant for this medicinal product is Zentiva, k.s.

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

Duloxetine Zentiva is a generic of Cymbalta, which has been authorised in the EU since 17 December 2004. Studies have demonstrated the satisfactory quality of Duloxetine Zentiva, 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 Zentiva is indicated in adults”.

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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