



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 October 2014  
EMA/CHMP/605915/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Duloxetine Lilly

## duloxetine

On 23 October 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation based on an informed consent application for the medicinal product Duloxetine Lilly (30 mg and 60 mg, gastro-resistant capsule). Duloxetine Lilly is intended for the treatment of major depressive disorder, diabetic peripheral neuropathic pain and generalised anxiety disorder. The applicant for this medicinal product is Eli Lilly Nederland B.V.

The active substance of Duloxetine Lilly, duloxetine, is a combined serotonin (5-HT) and noradrenaline (NA) reuptake inhibitor. It weakly inhibits dopamine reuptake with no significant affinity for histaminergic, dopaminergic, cholinergic and adrenergic receptors. Duloxetine dose-dependently increases extracellular levels of serotonin and noradrenaline in various brain areas.

The benefits with Duloxetine Lilly are its ability to reduce the symptoms of the below medical conditions. The most common side effects are nausea, dry mouth and constipation.

The approved indications are:

“Treatment of major depressive disorder.  
Treatment of diabetic peripheral neuropathic pain.  
Treatment of generalised anxiety disorder.

Duloxetine Lilly 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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Duloxetine Lilly and therefore recommends the granting of the marketing authorisation.