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**Public statement**

# Ariclaim

## Withdrawal of the marketing authorisation in the European Union

On 9 July 2018, the European Commission withdrew the marketing authorisation for Ariclaim (duloxetine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Eli Lilly Nederland B.V., which notified the European Commission of its decision not to market the product in the EU for commercial reasons.

Ariclaim was originally granted marketing authorisation in the EU on 11 August 2004 for treatment of stress urinary incontinence (SUI) and diabetic peripheral neuropathic pain. The marketing authorisation was initially valid for a 5-year period. It was renewed with unlimited validity in 2009 for the treatment of diabetic peripheral neuropathic pain but Ariclaim is no longer marketed in any EU country.

Ariclaim is identical to Cymbalta, Duloxetine Lilly and Xeristar, which are also authorised in the EU to treat diabetic peripheral neuropathic pain. The marketing authorisation holder will maintain the marketing authorisation for Cymbalta, Duloxetine Lilly and Xeristar.

The European Public Assessment Report (EPAR) for Ariclaim will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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