

23 April 2015
EMA/CHMP/249216/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Relistor methylnaltrexone bromide

On 23 April 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Relistor. The marketing authorisation holder for this medicinal product is TMC Pharma Services Ltd.

The CHMP adopted an extension to the existing indication as follows²:

"Relistor is indicated for the treatment of opioid-induced constipation ~~in advanced illness adult patients, aged 18 years and older, who are receiving palliative care~~ when response to ~~usual~~ laxative therapy has not been sufficient **in adult patients, aged 18 years and older.**"

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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

² New text in bold, removed text as strikethrough