23 July 2015
EMA/CHMP/442672/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Qutenza

capsaicin

On 23 July 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 Qutenza. The marketing authorisation holder for this medicinal product is Astellas Pharma Europe B.V.

The CHMP adopted an extension to the existing indication as follows[2]:

"Qutenza is indicated for the treatment of peripheral neuropathic pain in ~~non-diabetic~~ adults either alone or in combination with other medicinal products for pain."

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

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