27 May 2016
EMA/CHMP/178344/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Revestive

teduglutide

On 26 May 2016, 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 Revestive. The marketing authorisation holder for this medicinal product is NPS Pharma Holdings Limited.

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

"Revestive is indicated for the treatment of ~~adult~~ patients **aged 1 year and above** with short bowel syndrome. Patients should be stable following a period of intestinal adaptation ~~after surgery~~."

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 strikethrough

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