13 December 2018
EMA/845509/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rizmoic

naldemedine

On 13 December 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rizmoic, intended for the treatment of opioid-induced constipation (OIC). The applicant for this medicinal product is Shionogi B.V.

Rizmoic will be available as 200-microgram film-coated tablets. The active substance of Rizmoic is naldemedine, a peripherally-acting mu-opioid receptor antagonist which acts in tissues such as the gastrointestinal tract, thereby decreasing the constipating effects of opioids without reversing the central nervous system-mediated opioid effects.

The benefits with Rizmoic are its ability to induce a clinical relevant increase in the number of spontaneous bowel movements in patients suffering from opioid-induced constipation. The most common side effects are abdominal pain (7.8%), diarrhoea (5.9%), nausea (3.6%), and vomiting (1.1%).

The full indication is: “Rizmoic is indicated for the treatment of opioid-induced constipation (OIC) in adult patients who have previously been treated with a laxative”.

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.

[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

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