20 July 2017
EMA/CHMP/464835/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xermelo

telotristat ethyl

On 20 July 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Xermelo, intended for the treatment of carcinoid syndrome diarrhoea in combination with a somatostatin analogue. Xermelo was designated as an orphan medicinal product on 8 October 2009. The applicant for this medicinal product is Ipsen Pharma.

Xermelo will be available as 250-mg film-coated tablets. The active substance in Xermelo, telotristat ethyl, inhibits L-tryptophan hydroxylases (TPH1 and TPH2), which are the rate-limiting step in serotonin biosynthesis. Serotonin is over-secreted in patients with neuroendocrine tumours and carcinoid syndrome. Serotonin is thought to contribute to the symptoms associated with carcinoid syndrome.

The benefits with Xermelo are its ability to decrease the number of bowel movements per day in patients whose carcinoid syndrome diarrhoea cannot be managed with somatostatin analogues alone.

The most common side effects are abdominal pain, fatigue and increased gamma-glutamyl transferase (a liver enzyme).

The full indication is: "Xermelo is indicated for the treatment of carcinoid syndrome diarrhoea in combination with somatostatin analogue (SSA) therapy in adults inadequately controlled by SSA therapy".

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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