25 March 2021
EMA/CHMP/164792/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ponvory

ponesimod

On 25 March 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ponvory, intended for the treatment of active relapsing forms of multiple sclerosis. The applicant for this medicinal product is Janssen-Cilag International N.V.

Ponvory will be available as 2 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7 mg, 8 mg, 9 mg, 10 mg and 20 mg film-coated tablets. The active substance of Ponvory is ponesimod, a selective immunosuppressants (ATC code: L04AA). Ponesimod binds with high affinity to S1P receptor 1 located on lymphocytes, blocking the capacity of lymphocytes to egress from lymph nodes and reducing the number of lymphocytes in peripheral blood. The mechanism by which ponesimod exerts therapeutic effects in multiple sclerosis may involve the reduction of lymphocyte migration into the central nervous system (CNS).

The benefits of Ponvory are the prevention of relapses and the occurrence of new focal inflammatory lesions in the CNS. The most common side effects are upper respiratory tract and urinary infections, dyspnea and increased levels of alanine transaminase.

The full indication is:

> Ponvory is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features.

Ponvory should be initiated under the supervision of a physician experienced in the management of multiple sclerosis

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union