15 September 2022
EMA/CHMP/767279/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Teriflunomide Mylan

teriflunomide

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Teriflunomide Mylan, intended for the treatment of multiple sclerosis (MS). The applicant for this medicinal product is Mylan Pharmaceuticals Limited.

Teriflunomide Mylan will be available as a 14 mg film-coated tablet. The active substance of Teriflunomide Mylan is teriflunomide, a selective immunosuppressant (ATC code: L04AA31). The exact mechanism by which teriflunomide exerts its therapeutic effect in MS is not fully understood, but it is known to reduce the proliferation of lymphocytes by blocking the mitochondrial enzyme dihydroorotate dehydrogenase (DHO-DH).

Teriflunomide Mylan is a generic of Aubagio, which has been authorised in the EU since 26th of August 2013. Studies have demonstrated the satisfactory quality of Teriflunomide Mylan, and its bioequivalence to the reference product Aubagio. A question and answer document on generic medicines can be found here.

The full indication is:

> Teriflunomide Mylan is indicated for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing remitting multiple sclerosis (MS) (please refer to section 5.1 for important information on the population for which efficacy has been established).

Treatment with Teriflunomide Mylan should be initiated and supervised by 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