



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2022
EMA/CHMP/748820/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Teriflunomide Accord

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 Accord, intended for the treatment of multiple sclerosis (MS). The applicant for this medicinal product is Accord Healthcare S.L.U.

Teriflunomide Accord will be available as a 14 mg film-coated tablet. The active substance of Teriflunomide Accord 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 Accord 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 Accord, 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 Accord 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 Accord 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

