30 April 2020
EMA/CHMP/213580/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fingolimod Accord

fingolimod

On 30 April 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fingolimod Accord, intended for the treatment of relapsing-remitting multiple sclerosis with high disease activity. The applicant for this medicinal product is Accord Healthcare S.L.U.

Fingolimod Accord will be available as 0.5 mg hard capsules. The active substance of Fingolimod Accord is fingolimod hydrochloride, a selective immunosuppressant (ATC code: L04AA27) acting as a sphingosine 1-phosphate (S1P) receptor modulator. Fingolimod hydrochloride is metabolised to the active metabolite fingolimod phosphate, which blocks the capacity of lymphocytes to egress from lymph nodes and reduces the infiltration of pathogenic lymphocyte cells into the central nervous system.

Fingolimod Accord is a generic of Gilenya, which has been authorised in the EU since 17 March 2011. Studies have demonstrated the satisfactory quality of Fingolimod Accord and its bioequivalence to the reference product Gilenya. A question and answer document on generic medicines can be found here.

The full indication is:

> Fingolimod Accord as single disease modifying therapy in highly active relapsing remitting multiple sclerosis for the following groups of adult and paediatric patients aged 10 years and older, with a body weight of >40 kg:
>
> - Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy or
> - Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gd-enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

It is proposed that Fingolimod Accord be prescribed by physicians experienced in the treatment of multiple sclerosis.

Detailed recommendations for the use of this product will be described in the summary of product

[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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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.