



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 June 2017
EMA/CHMP/364898/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Mavenclad cladribine

On 22 June 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 Mavenclad, intended for the treatment of relapsing forms of multiple sclerosis. The applicant for this medicinal product is Merck Serono Europe Limited.

Mavenclad will be available as 10-mg tablets. The active substance of Mavenclad is cladribine, an antimetabolite (ATC code: L01BB04), which depletes lymphocytes by causing DNA strand breaks and interfering with DNA synthesis.

The benefits with Mavenclad are its ability to reduce the frequency of relapses and to delay disease progression. The most important side effects are lymphopenia, which can be severe and long-lasting, and infections, including herpes zoster.

The full indication is: "Treatment of adult patients with highly active relapsing multiple sclerosis (MS) as defined by clinical or imaging features".

Mavenclad must be initiated and supervised by a physician experienced in the treatment of MS.

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

