14 November 2019
EMA/CHMP/536390/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tavlesse

fostamatinib

On 14 November 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tavlesse, intended for the treatment of primary immune thrombocytopenia (ITP). This is an acquired immune-mediated disorder characterised by destruction of platelets and impaired platelet production.

The applicant for this medicinal product is Rigel Pharmaceuticals B.V.

Tavlesse will be available as 100-mg and 150-mg film-coated tablets. The active substance of Tavlesse is fostamatinib (ATC code: B02BX09). Fostamatinib blocks spleen tyrosine kinase (SYK), and thereby inhibits signal transduction of B-cell receptors and Fc-activating receptors, which play a key role in antibody-mediated cellular responses. Fostamatinib reduces antibody-mediated destruction of platelets.

The benefits of Tavlesse are its ability to increase and maintain platelet count and reduce bleeding risk. The most common side effects are dizziness, diarrhoea, nausea, frequent bowel movement, hypertension and blood pressure abnormalities and liver function test abnormalities.

The full indication is: "Tavlesse is indicated for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments". Fostamatinib treatment should be initiated and remain under the supervision of a physician who is experienced in the treatment of haematological diseases.

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

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