23 July 2026
EMADOC-1829012207-56485
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ruxolitinib Viatris

ruxolitinib

On 23 July 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ruxolitinib Viatris, intended for the treatment of myelofibrosis, polycythaemia vera and graft-versus-host disease.

The applicant for this medicinal product is Viatris Limited.

Ruxolitinib Viatris will be available as tablets (5, 10, 15 and 20 mg). The active substance of Ruxolitinib Viatris is ruxolitinib, a protein kinase inhibitor (ATC code: L01EJ01), the antineoplastic activity of which is linked to the selective inhibition of the Janus Associated Kinases (JAKs) involved in the signalling mediation of a number of cytokines and growth factors that are important for haematopoiesis and immune function.

Ruxolitinib Viatris is a generic of Jakavi, which has been authorised in the EU since 23 August 2012. Studies have demonstrated the satisfactory quality of Ruxolitinib Viatris, and its bioequivalence to the reference product Jakavi.

A question and answer document on generic medicines can be found here.

The full indication is:

Myelofibrosis (MF)

Ruxolitinib Viatris is indicated for the treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.

Polycythaemia vera (PV)

Ruxolitinib Viatris is indicated for the treatment of adult patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea.

Graft versus host disease (GvHD)

[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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Acute GvHD
Ruxolitinib Viatris is indicated for the treatment of adults and paediatric patients aged 28 days and older with acute graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

Chronic GvHD
Ruxolitinib Viatris is indicated for the treatment of adults and paediatric patients aged 6 months and older with chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).

Ruxolitinib Viatris should be prescribed by physicians experienced in the administration of anticancer medicinal products.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.