14 November 2024
EMA/CHMP/518145/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Jakavi

ruxolitinib

On 14 November 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Jakavi. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted an extension of indication for the treatment of paediatric patients with acute and chronic graft versus host disease (GvHD) together with a new pharmaceutical form, Jakavi 5 mg/mL oral solution. The oral solution is to be used by patients who cannot swallow tablets.

The full indication for Jakavi oral solution will be as follows:[2]

Graft versus host disease (GvHD)

Acute GvHD
Jakavi 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
Jakavi 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).

The full indications for Jakavi tablets will be as follows:[2]

Myelofibrosis (MF)

Jakavi 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)

[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
[2] New text in bold, removed text as strikethrough

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

Graft versus host disease (GvHD)

Acute GvHD

Jakavi 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

Jakavi 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).

~~Jakavi is indicated for the treatment of patients aged 12 years and older with acute graft versus host disease or chronic graft versus host disease who have inadequate response to corticosteroids or other systemic therapies (see section 5.1).~~

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.