



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 February 2026  
EMADOC-1829012207-42073  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Rhapsido remibrutinib

On 26 February 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 Rhapsido, intended for the treatment of adults with chronic spontaneous urticaria.

The applicant for this medicinal product is Novartis Europharm Limited.

Rhapsido will be available as a 25 mg film-coated tablet. The active substance of Rhapsido is remibrutinib, a selective immunosuppressant (ATC code: L04AA60). Remibrutinib is a Bruton's tyrosine kinase (BTK) inhibitor. In chronic spontaneous urticaria, it inhibits mast cell and basophil degranulation, including the release of histamine and other proinflammatory mediators, mediated by pathogenic IgE or IgG directed against the FcεR1 or IgE.

The benefits of Rhapsido are its ability to improve itch and hives, as shown by the change in weekly urticaria activity score (UAS7) after 12 weeks of treatment, compared with placebo, in two multicentre, randomised, double-blind, placebo-controlled phase 3 studies. The most common side effects with Rhapsido are upper respiratory tract infections, such as nasopharyngitis and influenza.

The full indication is:

Rhapsido is indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients with inadequate response to H1 antihistamine treatment.

Treatment with Rhapsido should be initiated by physicians experienced in the diagnosis and treatment of chronic spontaneous urticaria.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

