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Rhapsido (*remibrutinib*)

A plain-language overview of Rhapsido and why it is authorised in the EU

What is Rhapsido and what is it used for?

Rhapsido is a medicine used for treating chronic spontaneous urticaria, an itchy rash that occurs without an obvious trigger and lasts for at least 6 weeks. It is used in adults for whom treatment with H1 antihistamine (a common treatment for allergic symptoms) has not worked well enough.

Rhapsido contains the active substance remibrutinib.

How is Rhapsido used?

Rhapsido can only be obtained with a prescription, and treatment should be started by a doctor experienced in the diagnosis and treatment of chronic spontaneous urticaria.

Rhapsido is available as tablets to be taken by mouth twice a day. This is a long-term treatment; however, the doctor will regularly reassess the need for continued treatment and may stop it if there is no response after 24 weeks.

For more information about using Rhapsido, see the package leaflet or contact your doctor or pharmacist.

How does Rhapsido work?

The active substance in Rhapsido, remibrutinib, works by blocking an enzyme called Bruton's tyrosine kinase (BTK). By blocking BTK, Rhapsido stops the release of histamine and other substances causing inflammation in the body, which reduces the symptoms of chronic spontaneous urticaria.

What benefits of Rhapsido have been shown in studies?

In 2 main studies, Rhapsido was shown to reduce the symptoms of chronic spontaneous urticaria compared with placebo (a dummy treatment).

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The studies involved a total of 925 adults who had chronic spontaneous urticaria for at least 6 months and for whom H1 antihistamine treatment did not work well enough. They received either Rhapsido or placebo.

Both studies assessed improvement in itch and hives symptoms as reported by patients using a standard scale called 'urticaria activity score over 7 days' (UAS7). The scale ranges from 0 (no urticaria) to 42 (severe urticaria).

After 12 weeks of treatment, the UAS7 score in the first study decreased by an average of around 20 points in patients who took Rhapsido, compared with an average decrease of around 14 points in those who took placebo. In the second study, the score decreased by an average of about 19 points with Rhapsido, compared with an average decrease of about 12 points for placebo.

Studies carried out with Rhapsido are described in more detail in the medicine's assessment report.

What are the side effects and restrictions with Rhapsido?

For the full list of side effects and restrictions with Rhapsido, see the package leaflet.

The most common side effects with Rhapsido include upper respiratory tract infections (nose and throat infection, which may affect more than 1 in 10 people), including common cold and flu.

Bleeding, bruising, herpes virus infection, headache, nausea (feeling sick), abdominal (belly) and back pain and fever may occur in up to 1 in 10 people.

Why is Rhapsido authorised in the EU?

Rhapsido has been shown to provide meaningful improvement of chronic spontaneous urticaria symptoms in patients for whom standard H1 antihistamine treatment did not work well enough. However, data on the long-term effectiveness of treatment are limited due to the short duration of the studies and this will be further evaluated after authorisation. Side effects of Rhapsido, including infections and bleeding events, are known side effects of medicines targeting BTK; the package leaflet includes recommendations to manage these risks. The long-term safety of Rhapsido will also be further evaluated after authorisation.

The European Medicines Agency therefore decided that Rhapsido's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Rhapsido?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rhapsido have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rhapsido are continuously monitored. Suspected side effects reported with Rhapsido are carefully evaluated and any necessary action taken to protect patients.

Other information about Rhapsido

Rhapsido received a marketing authorisation valid throughout the EU on 23 April 2026.

Further information on Rhapsido, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rhapsido.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 05-2026.