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Brinsupri (*brensocatib*)

An overview of Brinsupri and why it is authorised in the EU

What is Brinsupri and what is it used for?

Brinsupri is a medicine used to treat non-cystic fibrosis bronchiectasis in people aged 12 years and older who had two or more exacerbations (flare-ups or worsening of symptoms) in the past 12 months. Non-cystic fibrosis bronchiectasis is a chronic (long-term) inflammatory lung disease that permanently damages the airways, leading to increased mucus production, repeated infections and persistent cough.

Brinsupri contains the active substance brensocatib.

How is Brinsupri used?

Brinsupri can only be obtained with a prescription and is available as a tablet to be taken by mouth once a day with or without food.

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

How does Brinsupri work?

In non-cystic fibrosis bronchiectasis, certain white blood cells called neutrophils release excessive amounts of inflammatory proteins in the airways, leading to lung damage. The active substance in Brinsupri, brensocatib, blocks a protein called dipeptidyl peptidase 1 (DPP1), which activates the inflammatory proteins inside neutrophils. By blocking DPP1, brensocatib reduces airway inflammation and lung damage in people with non-cystic fibrosis bronchiectasis.

What benefits of Brinsupri have been shown in studies?

Brinsupri was shown to be more effective than placebo (a dummy treatment) at reducing flare-ups of the disease in a main study. The study involved 1,767 people, including 41 adolescents aged 12 years and older, with non-cystic fibrosis bronchiectasis who had at least one (for adolescents) or two (for adults) exacerbations in the past 12 months. The main measure of effectiveness was the average number of pulmonary exacerbations in a year. An exacerbation was defined as at least three or more symptoms of the disease, such as increased cough, increased phlegm quantity and/or changes in

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consistency, and coughing up blood, lasting at least 2 days, which required treatment with an antibiotic. After one year of treatment, around 48.5% (279 out of 575) of people given Brinsupri remained free from exacerbations compared with around 40.3% (227 out of 563) of those given placebo. In addition, those given Brinsupri experienced their first exacerbation after an average of 51 weeks of treatment compared with 37 weeks for those given placebo.

What are the risks associated with Brinsupri?

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

The most common side effects with Brinsupri (which may affect up to 1 in 10 people) include headache, hyperkeratosis (thickening and toughening of the skin), dermatitis (inflammation of the skin), rash, upper respiratory tract (nose and throat) infections and dry skin.

Why is Brinsupri authorised in the EU?

At time of authorisation, there were no medicines authorised for treating people with non-cystic fibrosis bronchiectasis. Treatment was limited to managing the symptoms of the disease. Brinsupri was found to be effective at reducing the number of exacerbations of the disease, as well as delaying their onset. In terms of safety, the side effects of Brinsupri were generally mild to moderate and considered manageable. The European Medicines Agency therefore decided that Brinsupri'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 Brinsupri?

The company that markets Brinsupri must carry out a study to evaluate its long-term safety in people receiving the medicine.

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

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

Other information about Brinsupri

Brinsupri received a marketing authorisation valid throughout the EU on 18 November 2025.

Further information on Brinsupri can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/brinsupri.

This overview was last updated in 11-2025.