



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2023
EMA/CHMP/322106/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Lyfnua

gefapixant

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lyfnua, intended for the treatment of refractory or unexplained chronic cough in adult patients. The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Lyfnua will be available as a 45 mg film-coated tablet. The active substance of Lyfnua is gefapixant, a cough suppressant (ATC code: R05DB29). Gefapixant is a non-narcotic, peripherally active, selective antagonist of P2X3 receptors, which are ATP-gated ion channels found on sensory C fibres of the vagus nerve in the airways. Blockade of ATP signalling through P2X3 receptors reduces excessive sensory-nerve activation and excessive cough induced by extracellular ATP.

The key benefit of the treatment with Lyfnua is the reduction in the frequency of coughs per 24 hours, as shown in two phase 3, double-blind, placebo-controlled parallel assignment intervention studies evaluating the efficacy and safety of gefapixant in adults with refractory chronic cough or unexplained chronic cough. The most common side effects are a distortion, loss or reduction of the sense of taste.

The full indication is:

Lyfnua is indicated in adults for the treatment of refractory or unexplained chronic cough.

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

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

