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Lyfnua (*gefapixant*)

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

What is Lyfnua and what is it used for?

Lyfnua is a medicine used to treat adults with chronic (long-term) cough which is unexplained or for which other treatments have not worked.

The medicine contains the active substance gefapixant.

How is Lyfnua used?

Lyfnua is available as tablets to be taken by mouth twice a day; it can only be obtained with a prescription.

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

How does Lyfnua work?

In response to inflammation or airway irritation, cells within the lining of the airways produce high levels of a substance called ATP. ATP attaches to specific receptors (targets) on nerve cells in the airways, which stimulates the nerves and triggers the urge to cough. The active substance in Lyfnua, gefapixant, blocks these receptors and keeps the nerves from triggering the cough reflex.

What benefits of Lyfnua have been shown in studies?

The benefits of Lyfnua were investigated in two main studies involving 1,360 adults with chronic cough, who were given Lyfnua or placebo (a dummy treatment). Lyfnua was shown to be more effective than placebo at lowering the average number of times patients coughed per hour, measured over a 24-hour period. In the first study, after 12 weeks of treatment, the average number of coughs per hour in patients given Lyfnua went from 18.2 to 7.1 (a reduction of 61%) compared with a decrease from 22.8 to 10.3 (a reduction of 55%) in patients given placebo. In the second study, after 24 weeks of treatment, the average number of coughs per hour went from 18.6 to 6.8 (a reduction of 63%) in patients given Lyfnua compared with a decrease from 19.5 to 8.3 (a reduction of 57%) in patients given placebo.

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What are the risks associated with Lyfnua?

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

The most common side effects with Lyfnua (which may affect more than 1 in 10 people) include taste disorders: dysgeusia (changes in the sense of taste), ageusia (loss of sense of taste) and hypogeusia (reduced sense of taste).

Why is Lyfnua authorised in the EU?

Lyfnua showed a modest effect in terms of reducing the number of daily coughs in patients with chronic cough. Side effects with Lyfnua are considered manageable; the most common side effects concerned taste disorders and these generally resolved once patients stopped treatment. The European Medicines Agency therefore decided that Lyfnua's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Lyfnua

Lyfnua received a marketing authorisation valid throughout the EU on 15 September 2023.

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

This overview was last updated in 09-2023.