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Lyfnua® (active substance: gefapixant)

First authorisation in Switzerland: 24 May 2022

Medicinal product (film-coated tablets) for the treatment of refractory chronic cough or unexplained chronic cough in adults

About the medicine

The medicinal product Lyfnua, containing the active substance gefapixant, is used for the treatment of adults who have been suffering from a cough for longer than eight weeks (chronic cough) that has not eased after use of other medicinal products, or the cause of which is unexplained. The medicinal product is available subject to prescription by a doctor.

Mode of action

In inflammations of the respiratory tract, a specific molecule binds to the P2X3 receptor[1] of respiratory tract nerve cells. This triggers a signal which the nerve cells recognise as indicating damage. This signal is experienced by patients as irritation of the throat, which triggers the cough reflex.

The active substance gefapixant contained in the medicinal product Lyfnua is a P2X3 receptor antagonist[2]. It inhibits the activation of the P2X3 receptor, which is thought to be responsible for chronic cough. Through the mechanism of action of gefapixant, Lyfnua can relieve coughs.

Use

Lyfnua, with the active substance gefapixant, is a prescription-only medicine and has been authorised as film-coated tablets in the dosage strength 45 mg.

The recommended dose is two film-coated tablets containing 45 mg once a day. Lyfnua can be taken independently of meals (i.e. with or without food).

[1] A receptor is a protein or a protein complex located on the surface of, or inside, cells. When a specific substance binds to a receptor, a reaction is triggered in the cell.

[2] An antagonist blocks a receptor, thereby preventing a specific substance from binding to that receptor.

Treatment with Lyfnua is initiated and monitored by a healthcare professional with experience of chronic cough conditions.

Lyfnua should be used with caution in patients with known hypersensitivity to medicinal products containing active substances from the sulfonamide class of drugs.

The doctor will adjust the dose in patients with severely reduced renal function.

Efficacy

The efficacy of Lyfnua was investigated in two 52-week double-blind, placebo-controlled[3] studies in more than 1,200 patients suffering from chronic cough whose cough had not improved despite treatment, or where the cause was unexplained.

The patients were administered two film-coated tablets of Lyfnua – or, in the placebo group, two film-coated tablets with no active substance – once a day.

The study showed a greater decrease in coughing frequency for patients treated with Lyfnua versus those treated with placebo.

Precautions, undesirable effects & risks

Lyfnua must not be used in those who are hypersensitive to the active substance or any of the excipients or in the case of hypersensitivity to sulfonamides.

The most frequent adverse effects are dry mouth and impairment of the sense of taste (change, decrease or complete loss).

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The study showed that irritation of the throat was diminished and frequency of coughing reduced in patients who received Lyfnua.

Taking all the risks and precautions into account, and based on the available data, the benefits of Lyfnua outweigh the risks. Swissmedic has therefore authorised the medicinal product Lyfnua, with the active substance gefapixant, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Lyfnua®

Information for patients (package leaflet): Information for patients Lyfnua®

Healthcare professionals can answer any further questions.

[3] A placebo is a dummy drug with no active substance.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.