# YOUR GUIDE TO LYFNUA® ▼ (gefapixant)

LYFNUA® ▼ (gefapixant) 45 mg tablets

**Learn about clinical trial results, adverse reactions, and dosing** for your adult patients with refractory or unexplained chronic cough (RCC).

**LYFNUA is available by private prescription only in the UK and is not available via the NHS.**

▼ **REPORTING OF SIDE EFFECTS:** The medicine is subject to additional monitoring. Please consult the SmPC and risk minimisation materials for further information to minimise the risks associated with the use of the medicine before making any prescribing decisions. Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD (Tel: 0208 154 8000).

LYFNUA is indicated in adults for the treatment of refractory or unexplained chronic cough.[1]

**This information is intended for UK healthcare professionals.**

Please consult the SmPC for further information to minimise the risks associated with the use of the medicine before making any prescribing decisions.

Click here for UK prescribing information for LYFNUA®.



GB-OGM-00090 | Date of Preparation: February 2026

MSD

## A FIRST-IN-CLASS TREATMENT[2]

LYFNUA is a non-narcotic, primarily peripherally acting, selective antagonist of the P2X3 receptor proven to help reduce cough frequency in adult patients with RCC.[1–3]

# CLINICAL TRIAL RESULTS

**LYFNUA was evaluated in two phase 3 clinical trials, with primary efficacy periods at 12 (COUGH-1), and 24 weeks (COUGH-2).[1]**

### COUGH-1

**Primary endpoint (between-group): Reduction in 24-hour cough frequency at Week 12 relative to placebo: -18.52%* (95% CI: -32.76, -1.28; P=0.036)[1]**

Within-group reductions from baseline at Week 12[1]:

- **LYFNUA 45 mg twice daily: -61.35%**
- Placebo: -54.77%

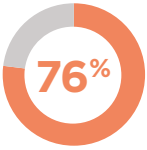
### COUGH-2

**Primary endpoint (between-group): Reduction in 24-hour cough frequency at Week 12 relative to placebo: -13.29%* (95% CI: -24.74, -0.10; P=0.048)[1]**

Within-group reductions from baseline at Week 12:[1]

- **LYFNUA 45 mg twice daily: -63.17%**
- Placebo: -57.19%

**The reduction in 24-hour cough frequency was observed by Week 4 and persisted through to 12 and 24 weeks[1]**




(332/439)

**76% OF PATIENTS** taking LYFNUA 45 mg twice daily in **COUGH-2** reported clinically meaningful improvement in their cough-specific quality of life.†[1]

**PLACEBO: 68%** estimated odds ratio vs placebo (95% CI): 1.46 (1.07, 1.99); estimated difference vs placebo (95% CI): 7.63 (1.34, 13.76); *P*=0.016.[1]

**COUGH-1 and COUGH-2:** Two 52-week, multicentre, randomised, double-blind, placebo-controlled studies of adults with RCC.[1] The primary objective was reduction in 24-hour cough frequency relative to placebo; secondary objectives included reduction in awake cough frequency and cough-specific quality of life.[1] The primary efficacy period of COUGH-1 was 12 weeks followed by a blinded extension period of 40 weeks (LYFNUA 45 mg: n=243, placebo: n=243).[1] The primary efficacy period of COUGH-2 was 24 weeks followed by a blinded extension period of 28 weeks (LYFNUA 45 mg: n=439, placebo: n=435).[1] Patients were randomised to twice-daily doses of LYFNUA 45 mg, 15 mg (not shown), or placebo.[1] Safety was evaluated in 1,369 patients from COUGH-1 and COUGH-2 treated with LYFNUA (15 mg or 45 mg twice daily) over 52 weeks.[1]

*Missing baseline values were imputed based on gender and region, followed by multiple imputation of the missing data (m=50 imputed datasets) for all follow-up visits using treatment, gender, region, and the other follow-up visits as covariates. Following imputation, an ANCOVA model was conducted at the time point of interest, adjusting for covariates of treatment, baseline, gender, and region.[1]

†The LCQ is a validated, multidimensional, patient-reported, health-related quality of life questionnaire commonly used in clinical studies assessing cough.[1,4] It evaluates physical, social, and psychological components of cough-specific quality of life.[5] A ≥1.3 point increase from baseline in LCQ total score was defined as clinically meaningful.[1]

# ADVERSE REACTIONS & DOSING

**LYFNUA is a non-narcotic with a safety profile established in two 52-week phase 3 clinical trials[1,2]**

## ADVERSE REACTIONS THAT OCCURRED IN PATIENTS TREATED WITH LYFNUA IN TWO PHASE 3 CLINICAL STUDIES (COUGH-1 AND COUGH-2)[6]:

The safety of gefapixant was evaluated in two phase 3 clinical studies (COUGH-1 and COUGH-2) of 52 week duration which included a total of 1 369 patients with RCC or UCC treated with gefapixant (15 mg or 45 mg twice daily).

- **Very common (≥1/10):** dysgeusia*, ageusia, hypogeusia
- **Common (≥1/100 to <1/10):** upper respiratory tract infection, decreased appetite, taste disorder, dizziness, headache†, cough‡, oropharyngeal pain, nausea, diarrhoea, dry mouth, salivary hypersecretion, abdominal pain upper, dyspepsia, hypoaesthesia oral paraesthesia oral, insomnia
- **Uncommon (≥1/1 000 to <1/100):** calculus urinary, nephrolithiasis nalculus bladder

*Dysgeusia was commonly reported as taste bitter, taste metallic or taste salty.
†Headache was reported in a phase 3b clinical study in female patients with C-SUI.
‡Cough includes reports of 'worsening', 'exacerbation', 'increase', or 'increased' cough.

## FOR THE MAJORITY OF PATIENTS WITH TASTE-RELATED ADVERSE REACTIONS:[1]


Onset of taste-related adverse reactions occurred within 9 days of starting LYFNUA

Most taste-related adverse reactions were reported as mild (65%) to moderate (32%) in intensity

- Taste-related adverse reactions resolved in 96% of patients with 25% reporting resolution on or before the last dose of LYFNUA[1]
- Adverse reactions resulting in discontinuation occurred in 22% of patients receiving LYFNUA[1]
- The most frequently reported adverse reactions leading to discontinuation of LYFNUA were dysgeusia (9%) and ageusia (4%)[1]

## THE RECOMMENDED DOSE OF LYFNUA IS ONE 45 MG TABLET TAKEN ORALLY TWICE DAILY WITH OR WITHOUT FOOD[1]. THE DOSAGE OF LYFNUA SHOULD BE ADJUSTED IN SOME PATIENTS WITH RENAL IMPAIRMENT:[1]

**MILD OR MODERATE**
(eGFR ≥30 mL/minute/1.73 $m^2$)

**No dose adjustment is required**

**SEVERE** (eGFR <30 mL/minute/1.73 $m^2$) not requiring dialysis

**One 45 mg tablet once daily**

Insufficient data are available in patients with end-stage renal disease requiring dialysis to make LYFNUA dosing recommendations.[1]

Patients should be instructed that if they miss a dose, they should skip the missed dose and go back to the regular schedule. Patients should not double their next dose or take more than the prescribed one.[1]

# KEY INFORMATION ABOUT LYFNUA


LYFNUA is a non-narcotic, primarily peripherally acting, selective antagonist of the P2X3 receptor[2,3]

The 24-hour cough frequency reduction was observed by Week 4 and persisted throughout 12 and 24 weeks[1]

LYFNUA may help reduce 24-hour cough frequency and improve patients' cough-specific quality of life[1]

The most common adverse reactions were taste related, and most of these were mild to moderate in intensity and resolved during treatment or upon discontinuation of LYFNUA[1]

Advise patients to take LYFNUA as directed: 45 mg twice daily with or without food[1]

Dose adjustment is required in patients with severe renal impairment (eGFR <30 mL/minute/1.73 $m^2$) not requiring dialysis[1]

**LYFNUA is available by private prescription only in the UK and is not available via the NHS.**

**Contact your MSD representative for further information or resources on LYFNUA.**

**References:**

**1.** LYFNUA® (gefapixant) Summary of Product Characteristics. 2025. **2.** Muccino DR and Green S. Pulm Pharmacol Ther. 2019; 56: 75–78. **3.** Richards D, et al. Br J Pharmacol. 2019; 176: 2279–2291. **4.** Morice A, et al. Eur Respir Rev. 2021; 30(162): 210127. **5.** Nguyen AM, et al. Ther Adv Respir Dis. 2022; 16: 1–13. **6.** McGarvey LP et al. Lancet. 2022;399:909-923.

**Abbreviations:**

**ANCOVA,** analysis of covariance; **CI,** confidence interval; **eGFR,** estimated Glomerular Filtration Rate; **LCQ,** Leicester Cough Questionnaire; **P2X3,** P2X purinoreceptor 3; **RCC,** refractory or unexplained chronic cough; **SmPC,** Summary of Product Characteristics.

Merck Sharp & Dohme (UK) Limited.
Registered Office: 120 Moorgate, London, EC2M 6UR, United Kingdom. Registered in England No. 233687.



MSD

GB-OGM-00090
Date of Preparation: February 2026

LYFNUA® (gefapixant) 45 mg tablets