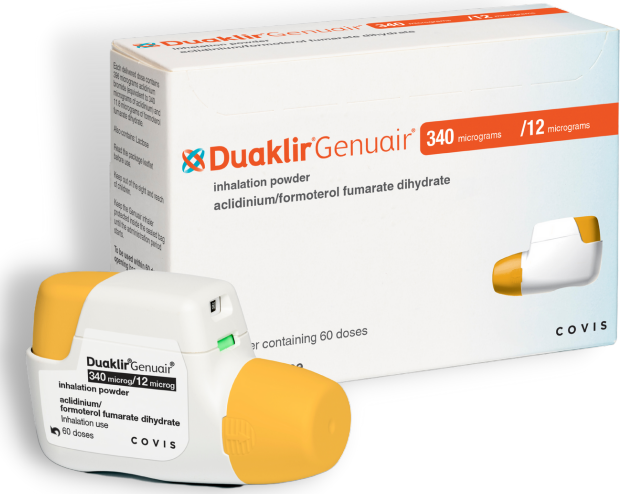
Duaklir® Genuair®

HELP YOUR COPD PATIENTS GET MOVING



Duaklir® Genuair® (aclidinium/formoterol fumarate dihydrate) has shown improvements for moderate intensity activities and in the number of steps per day of up to 731 vs placebo.[1]

Duaklir® Genuair® is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).[2]

Gold 2023

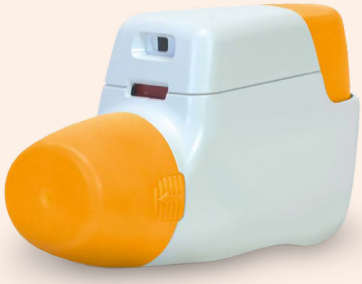
Gold 2023 positions a LABA/LAMA, such as Duaklir® Genuair® as optimal first line treatment for most patients for COPD.[3]

Initial Pharmacological Treatment

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalisation	Group E: LABA + LAMA consider LABA+LAMA+ICS if blood eos ≥ 300	
0 or 1 moderate exacerbations (not leading to hospital admission)	Group A: A bronchodilator mMRC 0-1, CAT < 10	Group B: LABA + LAMA mMRC ≥ 2, CAT ≥ 10

Duaklir® Genuair® Offers:

- **Twice a day dose, improved symptom control during night and day,** compared to placebo and monotherapies.[4]
- **No dose adjustment required** in patients with renal - or hepatic impairment or in elderly patients.[1]
- An **initial LABA/LAMA treatment** in accordance with the new **GOLD 2023** recommendations, for most treatment groups.[3]
- The benefit of the **Genuair®** inhaler with **high acceptability and confidence for patients as a result of easy use and the feedback system.**[5,6]



COVIS PHARMA ZENTIVA

Duaklir® Genuair®

Duaklir® Genuair®▼ 340 micrograms /12 micrograms, inhalation powder (aclidinium/formoterol fumarate dihydrate). Consult the full Summary of Product Characteristics before prescribing.

Presentation: Inhalation powder. Each delivered dose (the dose leaving the mouthpiece) contains396 micrograms aclidinium bromide (equivalent to 340 micrograms of aclidinium) and 11.8micrograms of formoterol fumarate dihydrate. Each delivered dose contains approximately 11 mg lactose (as monohydrate).

Indications: Duaklir Genuair is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Dosage and administration: The recommended dose is one inhalation twice daily. No dose adjustments are required in elderly patients or in patients with renal or hepatic impairment. Patients should be instructed on how to administer the product correctly as the inhaler may work differently from inhalers the patient has used previously. Consult SmPC Section 6.6 for the Instructions for Use. It is important to instruct the patients to read the Instructions for Use in the Package Leaflet.

Fertility, pregnancy and lactation: Should only be used during pregnancy and breast-feeding if the expected benefit to the woman is greater than any possible risks to the infant. It is unknown whether aclidinium (and/or its metabolites) or formoterol are excreted in human milk.

Contraindications: Hypersensitivity to the active substances or to the excipient lactose monohydrate.

Special warnings and precautions: Asthma: Duaklir Genuair should not be used. Paradoxical bronchospasm: If this occurs, Duaklir Genuair should be stopped and other treatments considered. Not for acute use: Duaklir Genuair is not indicated for the treatment of acute episodes of bronchospasm. Cardiovascular effects: Use with caution in patients with a myocardial infarction during the previous 6 months, unstable angina, newly diagnosed arrhythmia within the previous 3 months, QTc above 470 msec or hospitalisation within the previous 12 months for heart failure functional classes III and IV. B2-adrenergic agonists may produce increases in pulse rate and blood pressure, electrocardiogram (ECG) changes such as T wave flattening, ST segment depression and prolongation of the QTc- interval in some patients. If these effects occur, treatment may need to be discontinued. Long-acting β2-adrenergic agonists should be used with caution in patients with history of or known prolongation of the QTc-interval or treated with medicinal products affecting the QTc interval. Systemic effects: Use with caution in patients with severe cardiovascular disorders, convulsive disorders, thyrotoxicosis and phaeochromocytoma. Metabolic effects of hyperglycaemia and hypokalaemia may occur with high doses of β2-adrenergic agonists. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment. Hypokalaemia increases susceptibility to cardiac arrhythmias. Due to its anticholinergic activity, use with caution in patients with symptomatic prostatic hyperplasia, urinary retention or narrow-angle glaucoma. Dry mouth has been observed and may in the long term be associated with dental caries. Lactose content: Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take Duaklir Genuair.

Drug Interactions: COPD medicinal products: Co-administration with other anticholinergic and/or β2-adrenergic agonist containing medicinal products is not recommended. Hypokalaemic treatment: Caution is advised in concomitant treatment with methylxanthine derivatives, steroids, or non-potassium-sparing diuretics as this may potentiate the possible hypokalaemic effect of β2-adrenergic agonists. β-adrenergic blockers: β-adrenergic blockers may weaken or antagonise the effect of β-adrenergic agonists. If β-adrenergic blockers are required (including eye drops), cardioselective beta-adrenergic blockers are preferred, although these should be administered with caution.
Other interactions: Caution is advised in the concomitant administration of Duaklir Genuair with medicinal products known to prolong the QTc interval such as MAOIs, tricyclic antidepressants, antihistamines or macrolides. Concomitant use may potentiate the effect on the cardiovascular system and increase the risk of ventricular arrhythmias.

Effects on ability to drive/use machines: Duaklir Genuair has no or negligible influence on the ability to drive and use machines. The occurrence of blurred vision or dizziness may influence the ability to drive or use machines.

Undesirable effects: Consult SmPC for full list of side effects. Common: Nasopharyngitis, urinary tract infection, sinusitis, tooth abscess, insomnia, anxiety, headache, dizziness, tremor, cough, diarrhoea, nausea, dry mouth, myalgia, muscle spasms, blood creatine phosphokinase increased. Uncommon: Hypokalaemia, hyperglycaemia, agitation, dysgeusia, blurred vision, tachycardia, ECG QTc prolonged, palpitations, angina pectoris, dysphonia, throat irritation, stomatitis, rash, pruritus, urinary retention, blood pressure increased. Rare: Hypersensitivity, bronchospasm including paradoxical. Not known: Angioedema, anaphylactic reaction.

Pack size and UK list price:
Carton containing 1 inhaler (PLGB 53266/0002) with 60 doses: £32.50 (excluding VAT).

Legal category: POM

Marketing Authorisation Holder: Covis Pharma Europe B.V., Gustav Mahlerplein 2, 1082MA, Amsterdam, The Netherlands

Further Information is Available From: Covis Pharma Europe B.V., Gustav Mahlerplein 2, 1082MA, Amsterdam, The Netherlands

Date of Preparation: 29 Nov 2022
Ref: 000559924
RSP 19 0050

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Covis via email to medinfoEMEA@covispharma.com or via phone on 08004334029.

References:
1. Watz H, Troosters T, Beeh KM, et al. ACTIVATE: the effect of aclidinium/formoterol on hyperinflation, exercise capacity, and physical activity in patients with COPD. Int J Chron Obstruct Pulmon Dis. 2017;12:2545–2558.
2. Duaklir® Genuair® Summary of Product Characteristics. Available at https://mhraproducts4853.blob.core.windows.net/docs/b868873ea5e04f92aa9fefee1520b183dd956885 [last accessed June 2023].
3. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Gold Report 2023. Available at: https://goldcopd.org/2023-gold-report-2/ [last accessed June 2023].
4. Bateman ED, Chapman KR, Singh D, et al. Aclidinium bromide and formoterol fumarate as a fixed-dose combination in COPD: pooled analysis of symptoms and exacerbations from two six-month, multicentre, randomised studies (ACLIFORM and AUGMENT). Respir Res. 2015;16(1):92.
5. Chrystyn H, Niederlaender C. The Genuair® inhaler: a novel, multidose dry powder inhaler. Int J Clin Pract. 2012 Mar;66(3):309-17. doi: 10.1111/j.1742-1241.2011.02832.x. PMID: 22340451.
6. Magnussen H, Fyrnys B, Greguletz R. Genuair®/Pressair® Inhaler in COPD: The Patient Perspective. COPD. 2019 Apr;16(2):196-205. doi: 10.1080/15412555.2019.1630807. Epub 2019 Jul 2. PMID: 31264482.

For more information, or to order a placebo device contact
ukinfo@zentiva.com