Breathe better, morning & night.[1,2]

Twice daily dosing. Improvement of **early morning**, **day** and **night-time** COPD symptoms.[1,2*]

*compared to placebo and monocomponents

RAPID BRONCHODILATION within **5 minutes**[1,3]

LAMA + LABA

Brimica® Genuair®▼

aclidinium bromide + formoterol

Abbreviated Prescribing Information

Brimica® Genuair®▼ 340 micrograms/12 micrograms inhalation powder. Please consult the Summary of Product Characteristics (SPC) for the full prescribing information. **Presentation:** Inhalation powder in a white inhaler with an integral dose indicator and an orange dosage button. Each delivered dose contains 396 µg aclidinium bromide (equivalent to 340 µg of aclidinium) and 11.8 micrograms of formoterol fumarate dihydrate. Also, contains lactose. **Use:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage:** For inhalation use. Recommended dose is one inhalation of 340 µg/12 µg twice daily. Patients should be instructed on how to administer the product correctly as the Genuair inhaler may work differently from inhalers used previously. It is important to instruct the patients to read the Instructions for Use in the pack. No dose adjustments are required for elderly patients, or those with renal or hepatic impairment. No relevant use in children and adolescents. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Warnings and Precautions:** Do not use in asthma. Stop use if paradoxical bronchospasm occurs and consider other treatments. Do not use for the relief of acute episodes of bronchospasm. Use with caution in patients with myocardial infarction in the previous 6 months, unstable angina, newly diagnosed arrhythmia within the previous 3 months, or hospitalisation within the previous 12 months for heart failure functional classes III and IV. Discontinue if increases in pulse rate, blood pressure or changes in ECG occur. Use with caution in patients with a history of or known prolongation of the QTc interval or treated with products affecting the QTc interval. Use with caution in patients with severe cardiovascular disorders, convulsive disorders, thyrotoxicosis and phaeochromocytoma. Hypokalaemia may occur, is usually transient and supplementation not needed. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment. Use with caution in patients with symptomatic prostatic hyperplasia, urinary retention or with narrow-angle glaucoma. Dry mouth, observed with anticholinergic treatment, may be associated with dental caries in the long term. Do not use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Interactions:** Do not administer with other anticholinergic and/or long-acting β2-adrenergic agonist containing medicinal products. Caution in use with methylxanthine derivatives, steroids, non-potassium-sparing diuretics, β-adrenergic blockers or medicinal products known to prolong the QTc interval. Please consult the SPC for more details. **Fertility, pregnancy and lactation:** No data on use in pregnancy. Consider risk-benefit before using during lactation. Unlikely to affect fertility at the recommended dose. **Side-effects:** Common (1-10%): Nasopharyngitis, urinary tract infection, sinusitis tooth abscess, insomnia, anxiety, headache, dizziness, tremor, cough, diarrhoea, nausea, dry mouth, myalgia, muscle spasms, peripheral oedema, increased blood creatine phosphokinase. Uncommon (0.1- 1%): Hypokalaemia, hyperglycaemia, agitation, dysgeusia, blurred vision, tachycardia, electrocardiogram QTc prolonged, palpitations, angina pectoris, dysphonia, throat irritation, stomatitis, rash, pruritus, urinary retention, increased blood pressure. Rare (0.01-0.1%): Hypersensitivity, bronchospasm, including paradoxical. Not known: anaphylactic reaction, angioedema. **Pack sizes:** Carton containing 1 inhaler with 60 unit doses. **Legal category:** POM **Marketing Authorisation Number:** EU/1/14/963/001 **Marketing Authorisation holder:** AstraZeneca AB, SE-151 85 Södertälje, Sweden. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd., Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd. or may be found in the SPC. **Last updated:** October 2019

References: 1. Brimica® Genuair® Summary of Product Characteristics, last updated August 2019. **2.** Bateman, E.D., et al. Respir Res. 2015;16:92 **3.** D'Urzo, A.D., et al. Respir Res. 2014;15:123.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to A. Menarini Pharmaceuticals Ireland Ltd. Phone no: 01 284 6744.

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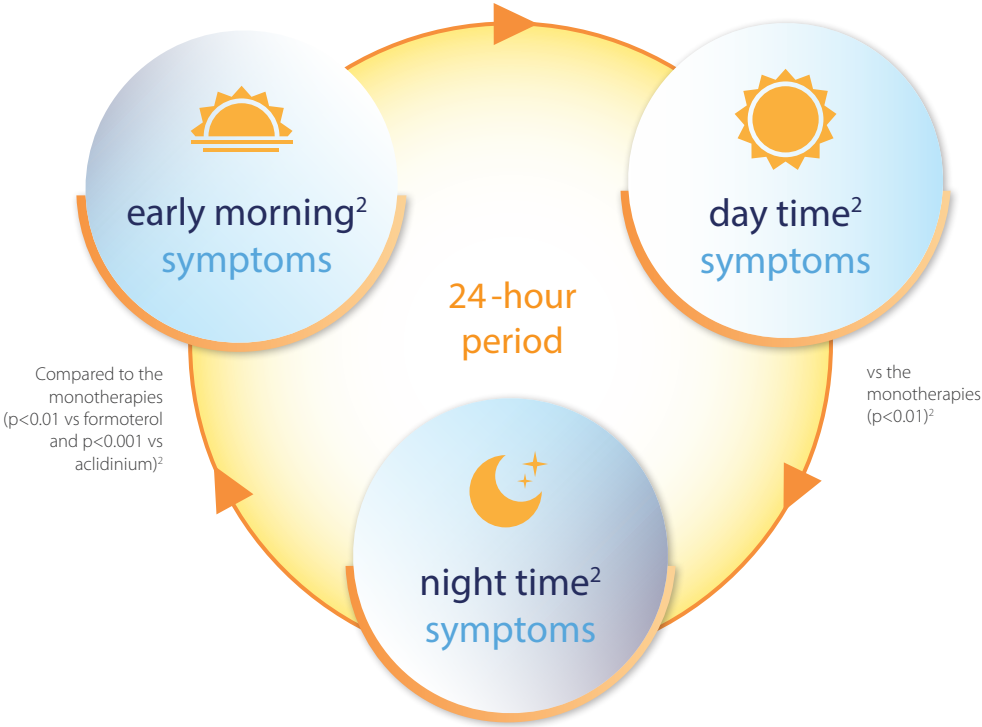
IR-BRI-18-2019

A.MENARINI
PHARMACEUTICALS IRELAND LTD
Healthcare for Life

Over 24 weeks Brimica® Genuair® significantly improved overall severity of:



"The symptom control achieved over a **24-hour period** with aclidinium/formoterol FDC may be as a result of its BID administration." [2]

Adapted from data in Reference 2. Two 24-week, double-blind, parallel-group, active-and placebo-controlled, multicentre, randomised Phase III studies. Patients ≥40 years with moderate to severe COPD FEV_1/FVC <70 % and FEV_1 ≥30 % but <80 % predicted normal were randomised (ACLIFORM: 2:2:2:2:1; AUGMENT: 1:1:1:1:1) to twice-daily aclidinium/formoterol 400/12 µg or 400/6 µg, aclidinium 400 µg, formoterol 12 µg or placebo. The pooled intent-to-treat population included 3394 patients. Coprimary endpoints were change from baseline to week 24 in FEV_1 and trough FEV_1 vs monotherapies in both studies. Daytime symptoms were assessed using the EXAcerbations of Chronic pulmonary disease Tool (EXACT) - Respiratory Symptoms (E-RS) questionnaire. E-RS total scores range from 0 to 40, with higher scores indicating more severe symptoms. Night-time and early-morning symptoms were recorded using newly developed questionnaires. The psychometric properties of these questionnaires have been evaluated and final tools developed (the Early-Morning Symptoms of COPD Instrument [EMSCI] and the Night-time Symptoms of COPD Instrument [NiSCI]). Scores ranged from 0 (no symptoms) to 4 (very severe symptoms). Note: 400/6 µg is not a licensed dose. BID, twice-daily; FDC, fixed-dose combination; FEV_1, forced expiratory volume in 1 sec; FVC, forced vital capacity.