

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



LAMA + LABA

Brimica®
Genuair®
aclidinium bromide + formoterol

RAPID
BRONCHODILATION
within

5
minutes^{1,3}

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, β₂-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 4. Vogelmeier C., et al. *Eur Respir J.* 2016;48:1030-1039.

▼ 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 HPRRA 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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A. MENARINI
PHARMACEUTICALS IRELAND LTD
Healthcare for Life

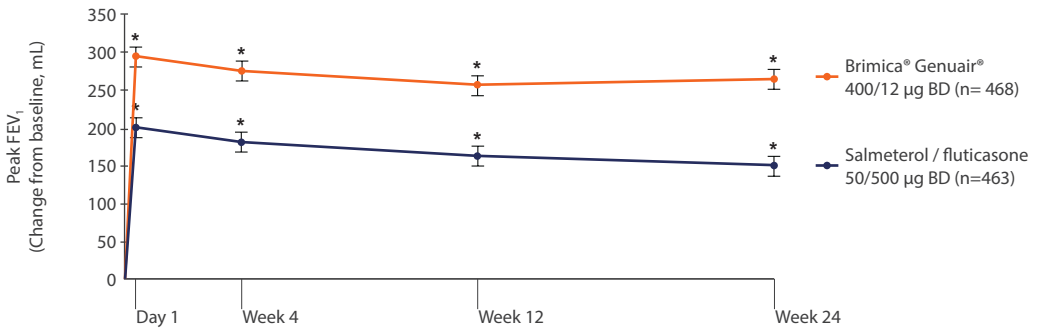
AFFIRM⁴

ACLIDINIUM AND FORMOTEROL
FINDINGS IN RESPIRATORY MEDICINE



AFFIRM demonstrated improved lung function with Brimica® Genuair® vs salmeterol / fluticasone (primary efficacy endpoint).^{4*}

*Change from baseline peak FEV₁ at week 24. Intention-to-treat population.⁴



Adapted from Figure 3 in reference 4. Randomised, double-blind, double-dummy, active-controlled, multicentre, phase 3b study conducted at 140 centres in 14 countries. 933 patients ≥ 40 years of age with a smoking history ≥ 10 pack-years and diagnosed with moderate-to-severe COPD were randomised (1:1) to acclidinium/formoterol 400/12 µg twice-daily or salmeterol/fluticasone 50/500 µg twice-daily. Efficacy end-points were peak FEV₁ (Primary) and Transition Dyspnoea Index (TDI) focal score (Secondary) at week 24. *, p<0.0001 for acclidinium/formoterol versus salmeterol/fluticasone. Patients who did not qualify for ICS treatment based on prior exacerbation history were included in the ICS/LABA arm. However, in clinical practice, it is common for patients to be treated with an ICS regardless of exacerbation history. BD, twice-daily; FEV₁, forced expiratory volume in 1 sec; ICS, inhaled corticosteroid; LABA, long-acting β_2 agonist.



Although the AFFIRM study was not powered for exacerbations[†], rates were similar in both groups.⁴

[†] Increase in symptoms for two or more consecutive days that required medical intervention such as increasing usual COPD medication, treatment with antibiotics and/or systemic corticosteroids, or hospitalisation.



While both treatments were well tolerated, ICS-related adverse events were less common with acclidinium/formoterol.⁴

ICS-related adverse events of interest.⁴

Adverse event	salmeterol/fluticasone (n=466)	Brimica® Genuair® (n=467)
Any event	50 (10.7%)	20 (4.3%)
Lower respiratory and lung infections	21 (4.5%)	7 (1.5%)
Bronchitis	6 (1.3%)	5 (1.1%)
Pneumonia	9 (1.9%)	3 (0.6%)

The most common adverse events were exacerbation of COPD (17.5%), headache (6.4%) and nasopharyngitis (5.8%), with similar proportions reported in each treatment group.⁴ ICS, inhaled corticosteroid.