

# **Emergency Medicine Physician**

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### PART OF THE NOVARTIS COPD PORTFOLIO



- **FEV.** improvement shown 5 minutes after first dose (0.093 L vs. placebo, p < 0.001, serial spirometry)<sup>1.3‡</sup>
- > Significantly greater LS mean FEV<sub>1</sub> vs. placebo demonstrated at all time points over 24 hours (LS mean FEV<sub>1</sub> [L] vs. placebo after first dose, p<0.001; time points were 5 min, 15 min, 30 min, 1 hr, 2 hrs, 3 hrs, 4 hrs, 6 hrs, 8 hrs, 10 hrs, 12 hrs, 23 hrs, 15 min, 23 hrs 45 min)<sup>4§</sup>

#### **Indication & clinical use:**

SEEBRI® BREEZHALER® is indicated as a long-term once-daily maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

- ▶ Not indicated for the relief of an acute deterioration of COPD
- Can be used at the recommended dose in elderly patients 65 years of age and older
- ▶ Should not be used in patients under 18 years of age

#### **Relevant warnings and precautions:**

- ▶ Not indicated for treatment of acute episodes of bronchospasm
- ▶ Not indicated for treatment of acutely deteriorating COPD
- ▶ Worsening of narrow-angle glaucoma
- ▶ Worsening of urinary retention
- ▶ In severe renal impairment, use only if the expected benefit outweighs the potential risk
- ▶ Paradoxical bronchospasm



PHARMACEUTICALS

Novartis Pharmaceuticals Canada Inc. Dorval, Québec H9S 1A9 www.novartis.ca ⇒ 514.631.6775 ⇒ 514.631.1867 SEEBRI and BREEZHALER are registered trademarks. Product Monograph available on request. 14SEE033E

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#### For more information:

Please consult the Product Monograph at <a href="www.novartis.ca/asknovartispharma/download.htm?res=seebri%20breezhaler\_scrip\_e.pdf&resTitleld=665">www.novartis.ca/asknovartispharma/download.htm?res=seebri%20breezhaler\_scrip\_e.pdf&resTitleld=665</a> for important information relating to adverse events, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling the Medical Information Department at 1-800-363-8883.

LAMA: long-acting muscarinic antagonist; COPD: chronic obstructive pulmonary disease; LS: least square; SGRQ: St. George's Respiratory Questionnaire, measures health-related quality of life in symptoms, activities and impact on daily life'; FEV; forced expiratory volume in 1 second.

- † GLOW2: A 52-week, randomized, double-blind, placebo-controlled parallel-group study of 1,060 patients with COPD. Patients received either SEEBRI® BREEZHALER® (glycopyrronium 50 mcg o.d.; n=525), placebo (n=268), or open-label tiotropium (18 mcg o.d.; n=267) as an active control. Primary endpoint was 24-hour post-dose (trough) FEV<sub>1</sub> following 12 weeks of treatment.
- ‡ GLOW1: A 26-week, randomized, double-blind, placebo-controlled parallel-group study to assess the efficacy, safety and tolerability of once-daily SEEBRI® BREEZHALER® (50 mcg) in patients with COPD (n=550); placebo (n=267).
- § LS mean FEV, (L) after first dose; SEEBRI\*\* BREZHALER\*\* (n=169) vs. placebo (n=83), respectively; 5 min; 1.39 vs. 1.30; 15 min; 1.43 vs. 1.28; 30 min; 1.44 vs. 1.28; 1 hr; 1.47 vs. 1.28; 2 hrs; 1.53 vs. 1.34; 3 hrs; 1.53 vs. 1.35; 4 hrs; 1.52 vs. 1.35; 6 hrs; 1.48 vs. 1.33; 8 hrs; 1.47 vs. 1.33; 10 hrs; 1.47 vs. 1.32; 12 hrs; 1.45 vs. 1.31; 23 hrs 15 min; 1.37 vs. 1.27; 23 hrs 45 min; 1.39 vs. 1.31;  $\rho$ <0.001 for all time points.

References: 1. SEEBR\()\* BREEZHALER\(^2\) Product Monograph. Novartis Pharmaceuticals Canada Inc., December 3, 2013. 2. Kerwin E, H\(\)ébert J, Gallagher N et al. Efficacy and safety of NWA237 versus placebo and tiotropium in patients with COPD: the GLOW2 study. Eur Respir J 2012-40:1106-14. 3. D'Utzo A, Fergisson GT, van Noord JA et al. Efficacy and safety of once-daily NWA237 in patients with moderate-to-severe COPD: the GLOW1 trial. Respir Res 2011;12(156):1-13. 4. Data on file. Novartis Pharmaceuticals Canada Inc. 5. Jones P. St. George's Respiratory Questionnaire Manual. Available from: www.healthstatus.sgul.ac.uk/SGRQ\_download/SGRQ\(^2\)20 Manual\(^2\)2010 University Accessed May 16, 2014.



\***seebri breezhaler**Glycopyrronium inhalation powder

