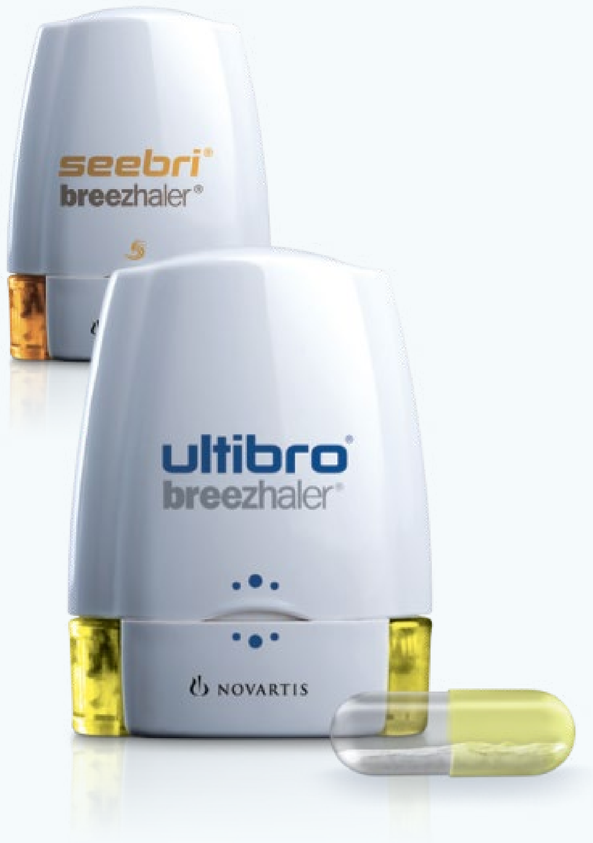


NEW ADDITIONS TO OUR COVIS RESPIRATORY PORTFOLIO

Two treatment options for COPD

ONCE DAILY
Pr ultibro® breezhaler®
indacaterol maleate/glycopyrronium bromide inhalation powder

ULTIBRO® BREEZHALER® (indacaterol maleate and glycopyrronium bromide) is a combination of a long-acting ß2-agonist (LABA) and a long-acting muscarinic antagonist (LAMA), indicated for the long-term once-daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema, and for the reduction of exacerbations of COPD in patients with a history of exacerbations.

Once Daily
Pr seebri® breezhaler®
Glycopyrronium inhalation powder

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

ULTIBRO® BREEZHALER®

SEEBRI® BREEZHALER®

ULTIBRO® BREEZHALER®

A Once-Daily LAMA/LABA[2†]

Recommended Dose[2†]

- **Once-daily oral inhalation** of the content of one 110/50 mcg capsule using the ULTIBRO® BREEZHALER® inhaler.[2]

Pharmacodynamic Profile*

- Rapid onset of bronchodilation within **5 minutes** post-dose.[2]
- Bronchodilation effect remained constant for **24 hours**.[2]
- The mean bronchodilator effect derived from serial FEV_1 measurements over 24 h was greater by 0.32 L compared to placebo after 26 weeks of treatment

Indication includes the reduction of COPD exacerbation in patients with a history of exacerbation

* Clinical significance is unknown

†Please refer to the product monograph for complete dosing and administration information.

SEEBRI® BREEZHALER®

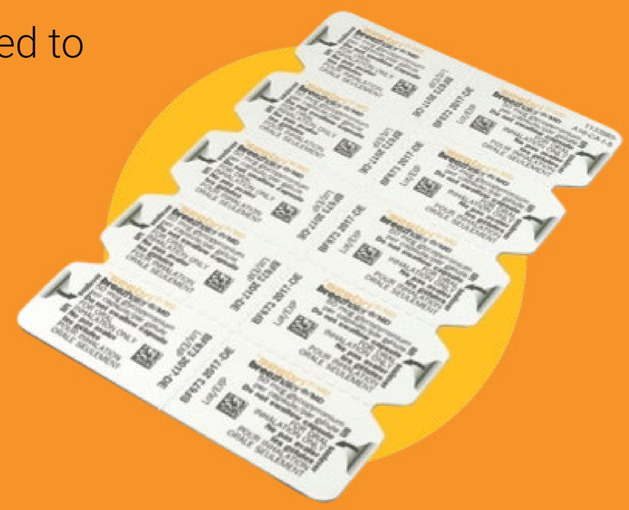
A Once-Daily LAMA[1*]

Recommended Dose[1*]

- **Once-daily oral inhalation** of the content of one 50 mcg capsule using the SEEBRI® BREEZHALER® inhaler.[1]

User-Friendly Blister Packaging

- **The blister packaging** was designed to facilitate removal of the capsule
- **Perforated edges** designed to facilitate separation
- **Improved design** to help identify the foil tab
- **Foil peels** open to access individual clear capsule

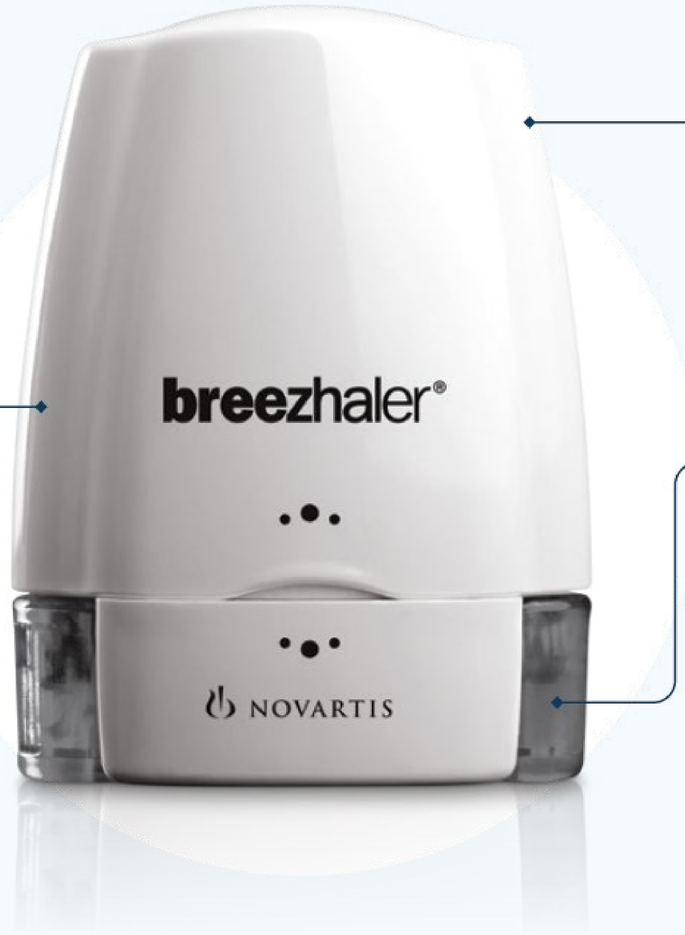


*Please refer to the product monograph for complete dosing and administration information.

THE BREEZHALER® IS DESIGNED SO PATIENTS CAN CONFIRM IF THEY'VE TAKEN THEIR MEDICATION CORRECTLY

Hear

the click when the capsule is pierced and the whirring sound during inhalation



Taste

You may taste the medicine as you inhale.

See

the clear capsule after inhalation to confirm that the full dose has been taken

Before **After**

ADMINISTRATION

ULTIBRO® BREEZHALER® or SEEBRI® BREEZHALER® are recommended for once-daily administration at the same time each day.

ULTIBRO® BREEEZHALER® or SEEBRI® BREEZHALER® capsules must be administered only by the oral inhalation route and only using the BREEZHALER® inhaler.

Capsules must not be swallowed

ULTIBRO® BREEZHALER® and SEEBRI® BREEZHALER® capsules must always be stored in the blister to protect from moisture, and only removed IMMEDIATELY BEFORE USE.

When prescribing ULTIBRO® BREEZHALER® or SEEBRI® BREEZHALER®, patients should be instructed on the correct use of the inhaler.

Patients who do not experience improvement in breathing should be asked if they are swallowing the medicine rather than inhaling it.

If a dose is missed, it should be taken as soon as possible. Patients should be instructed not to take more than one dose in a day.

For detailed information on the proper use of this medication, please refer to the Product Monograph and instruct your patients to refer to the information that is provided in their medication package.

Important Safety Information for ULTIBRO® BREEZHALER®

Clinical use:
- Not indicated for the treatment of acute episodes of bronchospasm
- Not indicated for asthma use
- Can be used at the recommended dose in elderly patients over 65 years of age
- Should not be used in patients under 18 years of age

Contraindications:
- Hypersensitivity to indacaterol maleate or glycopyrronium bromide, or to any other component of ULTIBRO® BREEZHALER®
- Severe hypersensitivity to milk proteins
- Not indicated for treatment of asthma

Most serious warnings and precautions:
Asthma-related death: Increased risk of asthma-related death is considered a class effect with LABAs, including indacaterol maleate. ULTIBRO® BREEZHALER® is not indicated for asthma.

Other relevant warnings and precautions:
- Not indicated for treatment of acute episodes of bronchospasm: patients who have been taking inhaled, short-acting bronchodilators on a regular basis should be instructed to discontinue regular use when beginning treatment with ULTIBRO® BREEZHALER®
- Not indicated for treatment of acutely deteriorating COPD
- Not to be used more often or at higher doses than recommended or with other LABA or LAMA products:
- Occurrence of dizziness or blurred vision may influence the ability to drive and use machinery
- Caution in patients with narrow-angle glaucoma: patients should be cautioned to avoid getting the drug powder into their eyes and to be alert of signs and symptoms of acute narrow angle glaucoma
- Caution in urinary retention: risk of prostatic hyperplasia and bladder neck obstruction
- Caution in patients with cardiovascular disorders, coronary insufficiency, acute myocardial infarction, cardiac arrhythmias, and hypertension: ULTIBRO® BREEZHALER® may need to be discontinued
- Caution in patients with a known history of QTc prolongation, risk factors for torsade de pointes, or taking medications known to prolong the QTc interval
- Caution in patients with convulsive disorders, thyrotoxicosis, and patients who are unusually responsive to sympathomimetic amines
- Risk of hypokalemia: monitor serum potassium in patients predisposed to low levels of serum potassium
- Risk of hyperglycemia: monitor blood glucose in diabetic patients
- Risk of immediate hypersensitivity reactions: discontinue immediately and do not rechallenge with ULTIBRO® BREEZHALER®
- Risk of angioedema
- In severe renal impairment (estimated GFR <30 mL/min/1.73m^2) including those with end-stage renal disease requiring dialysis, use only if the expected benefit outweighs the potential risk
- Risk of paradoxical bronchospasm: discontinue immediately
- May inhibit labour: use only if the potential benefit justifies the potential risk
- Pregnancy/nursing and delivery: use only if potential benefit justifies the potential risk
- Caution in patients with severe hepatic impairment
- ULTIBRO® BREEZHALER® capsules must not be swallowed

For more information:
Please consult the Product Monograph at https://pdf.hres.ca/dpd_pm/00054946.PDF 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.

Important Safety Information for SEEBRI® BREEZHALER®

Clinical use:

- 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

Contraindications:

- Hypersensitivity to glycopyrronium, or to any other component of SEEBRI® BREEZHALER®
- Severe hypersensitivity to milk proteins

Relevant warnings and precautions:

- Not indicated for treatment of acute episodes of bronchospasm
- Should not be initiated in patients with acutely deteriorating COPD
- Not to be used with other LAMAs
- Caution in patients with unstable ischemic heart disease, left ventricular failure, history of myocardial infarction, arrhythmia (excluding chronic stable atrial fibrillation), a history of long QT syndrome or whose QTc was prolonged at screening: SEEBRI® BREEZHALER® may need to be discontinued
- Risk of immediate hypersensitivity reactions: discontinue immediately if signs suggesting allergic reactions occur, in particular angioedema, urticaria or skin rash
- Caution in patients with narrow-angle glaucoma
- Caution in patients with urinary retention
- In severe renal impairment (estimated GFR <30 mL/min/1.73m^2), use only if the expected benefit outweighs the potential risk
- Risk of paradoxical bronchospasm: discontinue immediately
- SEEBRI® BREEZHALER® capsules must not be swallowed

For more information:

Please consult the Product Monograph at https://pdf.hres.ca/dpd_pm/00036566.PDF 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.

References: 1. SEEBRI® BREEZHALER® Product Monograph. Novartis Pharmaceuticals Canada Inc., September 29, 2016. **2.** ULTIBRO® BREEZHALER® Product Monograph. Novartis Pharmaceuticals Canada Inc., January 2020.

COVIS PHARMA

REVIEWED BY PAAB

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