ENERZAIR® BREEZHALER® & ATECTURA® BREEZHALER®

ASTHMA PRODUCTS USING THE BREEZHALER® DEVICE

LABA-LAMA-ICS

ENERZAIR® BREEZHALER®:

(indacaterol/glycopyrronium/mometasone furoate) is indicated as a maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a LABA and a medium or high dose of an ICS who experienced one or more asthma exacerbations in the previous 12 months

LABA-ICS

ATECTURA® BREEZHALER®:

(indacaterol/mometasone furoate) is a combination of a LABA and an ICS indicated as a once-daily maintenance treatment of asthma in adults and adolescents 12 years of age and older with reversible obstructive airways disease

valeo PHARMA

THIS GUIDE OUTLINES:

ONCE-DAILY ENERZAIR® BREEZHALER®

ONCE DAILY
ENERZAIR®
breezhaler®
Indacaterol (as acetate) / glycopyrronium (as bromide) / mometasone furoate inhalation powder

INDICATION

ENERZAIR® BREEZHALER® (indacaterol/glycopyrronium/mometasone furoate) is indicated as a maintenance treatment of asthma in **adult patients not adequately controlled with a maintenance combination of a LABA and a medium or high dose of an ICS who experienced one or more asthma exacerbations in the previous 12 months**

PRODUCT

150/50/160 µg indacaterol/glycopyrronium/mometasone furoate

RECOMMENDED DOSE

For patients ≥18 years of age, inhale the content of **ONE CAPSULE, ONCE A DAY** at the same time of the day each day (irrespective of time)

The maximum recommended dose is ENERZAIR® BREEZHALER® 150/50/160 µg once-daily

SUMMARY OF DOSING CONSIDERATIONS

Refer to Product Monograph for complete dosage and administration information

- ENERZAIR® BREEZHALER® should be used regularly even when asymptomatic
- ENERZAIR® BREEZHALER® should not be used more often or at higher doses than recommended, nor in conjunction with other medicines containing LABA
- Patients should discontinue regular use of rapid onset, short duration inhaled $beta_2$-agonists and use only for acute symptomatic relief
- ENERZAIR® BREEZHALER® should **not** be used to treat acute symptoms of asthma. Patients should be prescribed a rapid onset, short duration inhaled bronchodilator to relieve acute symptoms
- Dose Adjustment:
  - No dose adjustment is required in patients with mild to moderate renal or hepatic impairment
  - In patients with severe hepatic or renal impairment, ENERZAIR® BREEZHALER® should be used only if the expected benefit outweighs the potential risk
  - No dose adjustment is required in patients ≥65 years
  - Safety and efficacy in patients <18 years have not been established

ICS: inhaled corticosteroid; LABA: long-acting $beta_2$-agonist.

ONCE-DAILY ATECTURA® BREEZHALER®

ONCE DAILY ATECTURA® breezhaler®
Indacaterol (as acetate) / mometasone furoate inhalation powder

INDICATION

ATECTURA® BREEZHALER® (indacaterol/mometasone furoate) is a combination of a LABA and an ICS indicated as a once-daily maintenance treatment of asthma in **adults and adolescents 12 years of age and older with reversible obstructive airways disease**

ATECTURA® BREEZHALER® should be prescribed for: Patients not adequately controlled on a long-term asthma control medication, such as ICS or whose disease severity clearly warrants treatment with both a LABA and an ICS

PRODUCT

Low dose: 150/80 µg indacaterol/mometasone furoate

Medium dose: 150/160 µg indacaterol/mometasone furoate

High dose: 150/320 µg indacaterol/mometasone furoate

RECOMMENDED DOSE

For patients ≥12 years of age, inhale the content of **ONE CAPSULE, ONCE A DAY** at the same time of the day each day (irrespective of time)

ATECTURA® BREEZHALER®

150/80 µg once-daily is recommended in patients who require a combination of a LABA and a low dose of ICS

150/160 µg or 150/320 µg once-daily is recommended in patients who require a combination of a LABA and a medium or high dose of ICS

The maximum recommended dose is ATECTURA® BREEZHALER® 150/320 µg once-daily

SUMMARY OF DOSING CONSIDERATIONS

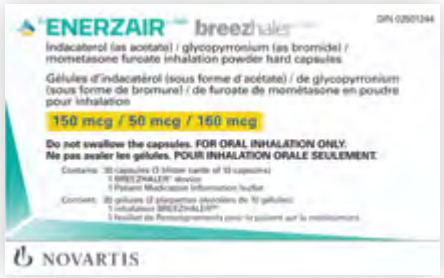
Refer to Product Monograph for complete dosage and administration information

- ATECTURA® BREEZHALER® should be used regularly even when asymptomatic
- Patients should be given the strength of ATECTURA® BREEZHALER® containing the appropriate mometasone furoate dosage for the severity of their disease and should be regularly reassessed by a healthcare professional
- ATECTURA® BREEZHALER® should **not** be used more often or at higher doses than recommended, nor in conjunction with other medicines containing LABA
- Patients should discontinue regular use of rapid onset, short duration inhaled $beta_2$-agonists and use only for acute symptomatic relief
- ATECTURA® BREEZHALER® should not be used to treat acute symptoms of asthma. Patients should be prescribed a rapid onset, short duration inhaled bronchodilator to relieve acute symptoms
- Dose Adjustment:
  - No dose adjustment is required in patients with renal impairment or mild or moderate hepatic impairment
  - In patients with severe hepatic impairment, ATECTURA® BREEZHALER® should be used only if the expected benefit outweighs the potential risk
  - No dose adjustment is required in patients ≥65 years
  - Safety and efficacy in patients <12 years have not been established

ICS: inhaled corticosteroid; LABA: long-acting $beta_2$-agonist.

ENERZAIR® BREEZHALER® AND ATECTURA® BREEZHALER®: WHAT'S INSIDE?

INCLUDES 30 CAPSULES AND BREEZHALER® IN ONE PACK



The product images shown are for illustration purposes only and may not be an exact representation of the product.

HOW TO USE THE ENERZAIR® BREEZHALER® AND ATECTURA® BREEZHALER® DEVICE

THE BREEZHALER® DEVICE IS DESIGNED SO PATIENTS CAN CONFIRM IF THE FULL DOSE HAS BEEN CORRECTLY ADMINISTERED

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

TASTE the medication upon inhalation

SEE the transparent capsule after inhalation to confirm there is no powder remaining:

Additional Important Information

- Capsules must always be stored in the blister card and only removed immediately before use
- Do not use capsules with any other inhaler
- Do not use the BREEZHALER® inhaler to take any other capsule medicine
- Never place the capsule in your mouth or the inhaler mouthpiece
- Do not blow into the mouthpiece
- Do not press the side buttons while inhaling through the mouthpiece
- Do not handle capsules with wet hands
- Never wash your inhaler with water

ADMINISTRATION STEPS

1 INSERT

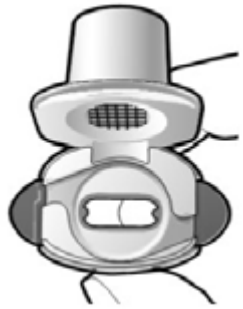
Open inhaler, remove capsule by peeling open blister pack. Do not push capsule through foil. **Do not swallow the capsule.** Insert capsule into chamber.

2 PIERCE AND RELEASE

Pierce capsule **only once** by firmly pressing both side buttons at the same time. Release side buttons.

3 INHALE DEEPLY

Breathe out fully. Place mouthpiece in your mouth, closing lips firmly around it. Inhale quickly and deeply. Hold your breath for up to 5 seconds. Rinse mouth with water after each dose and spit out.



4 CHECK CAPSULE IS EMPTY

Open the inhaler to see if there is any powder left in the capsule. **If there is powder left in the capsule, close the inhaler and repeat inhalation.** Remove empty capsule, close inhaler and replace the cap.

For complete information on the proper use of these medications, please refer to the Product Monographs:

ENERZAIR® BREEZHALER® | **ATECTURA® BREEZHALER®**

IMPORTANT SAFETY INFORMATION

ENERZAIR® BREEZHALER®

Consult the Product Monograph at **https://pdf.hres.ca/dpd_pm/00063748.PDF** for important information on:

- Contraindication in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Relevant warnings and precautions regarding serious asthma-related events, treatment of acute asthma symptoms, acutely deteriorating asthma, stopping ENERZAIR® BREEZHALER®, excessive use and use with other LABA products, worsening of narrow-angle glaucoma, worsening of urinary retention, cardiovascular effects, patients with known or suspected prolongation of the QT interval, localized infections of the mouth and throat, systemic corticosteroid effects, hypercorticism and adrenal suppression, adrenal insufficiency after transfer from systemic to inhaled corticosteroids, reduction in bone mineral density and monitoring requirements, hyperglycemia and monitoring requirements, hypokalemia and monitoring requirements, co-existing conditions, eosinophilic conditions, hypersensitivity, infections, monitoring and laboratory tests for serum potassium levels, blood glucose in diabetic patients, bone and ocular effects in patients at risk, and corticosteroid effects for patients with severe hepatic impairment, risks associated with established glaucoma, paradoxical bronchospasm, use in pregnant and breast-feeding women, and hepatic and renal impairment.
- Conditions of clinical use, adverse reactions, drug interactions and dosing instructions.

ONCE DAILY ENERZAIR® breezhaler®
Indacaterol (as acetate) / glycopyrronium (as bromide) / mometasone furoate inhalation powder

The Product Monograph is also available by calling Valeo Pharma at **1-855-694-0151**

ATECTURA® BREEZHALER®

Consult the Product Monograph at **https://pdf.hres.ca/dpd_pm/00063537.PDF** for important information on:

- Contraindication in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
- Relevant warnings and precautions regarding serious asthma-related events, treatment of acute asthma symptoms, acutely deteriorating asthma, stopping ATECTURA® BREEZHALER®, excessive use and use with other LABA products, cardiovascular effects, patients with known or suspected prolongation of the QT interval, localized infections of the mouth and throat, systemic corticosteroid effects, effect on growth, hypercorticism and adrenal suppression, adrenal insufficiency after transfer from systemic to inhaled corticosteroids, reduction in bone mineral density and monitoring requirements, hyperglycemia and monitoring requirements, hypokalemia and monitoring requirements, co-existing conditions, eosinophilic conditions, hypersensitivity, infections, monitoring and laboratory tests for serum potassium levels, blood glucose in diabetic patients, bone and ocular effects in patients at risk, and corticosteroid effects for patients with severe hepatic impairment, risks associated with established glaucoma, paradoxical bronchospasm, use in pregnant and breast-feeding women, and hepatic and renal impairment.
- Conditions of clinical use, adverse reactions, drug interactions and dosing instructions.

ONCE DAILY ATECTURA® breezhaler®
Indacaterol (as acetate) / mometasone furoate inhalation powder

The Product Monograph is also available by calling Valeo Pharma at **1-855-694-0151**

ICS: inhaled corticosteroid; LABA: long-acting beta$_2$-agonist; LAMA: long-acting muscarinic antagonist.

References:

1. ENERZAIR® BREEZHALER® Product Monograph. Novartis Pharmaceuticals Canada Inc. November 25, 2021.
2. ATECTURA® BREEZHALER® Product Monograph. Novartis Pharmaceuticals Canada Inc. November 12, 2021.

REVIEWED BY PAAB

MEMBER OF INNOVATIVE MEDICINES CANADA

valeo PHARMA

118280/E

HCP6/E