

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrENERZAIR® BREEZHALER®

Indacaterol (as acetate) / glycopyrronium (as bromide) / mometasone furoate inhalation powder hard capsules

Read this carefully before you start taking **ENERZAIR® BREEZHALER®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ENERZAIR BREEZHALER**.

What is ENERZAIR BREEZHALER used for?

ENERZAIR BREEZHALER is a combination of a long-acting beta₂-adrenergic agonist (LABA), a long-acting muscarinic antagonist (LAMA) and an inhaled corticosteroid (ICS). It is used as a maintenance treatment for asthma in adults:

- whose asthma is not being adequately controlled with a maintenance long-acting beta₂-agonist (LABA) and a medium or high dose of an inhaled corticosteroid (ICS)
- who have experienced one or more asthma attacks in the previous year

You should not take this medication:

- for the relief of the sudden (acute) symptoms of asthma (i.e. as rescue therapy for the treatment of sudden episodes of bronchospasm)

How does ENERZAIR BREEZHALER work?

ENERZAIR BREEZHALER contains 3 medicinal ingredients:

- indacaterol – a long-acting beta₂ agonist (LABA)
- glycopyrronium – a long-acting muscarinic antagonist (LAMA)
- mometasone furoate – an inhaled corticosteroid (ICS)

Indacaterol and glycopyrronium belong to a group of medicines called bronchodilators. They relax the muscles of the small airways in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When it is taken regularly, it helps the small airways to remain open.

Mometasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Corticosteroids reduce inflammation. They reduce the swelling and irritation in the small airways in the lungs and gradually ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

What are the ingredients in ENERZAIR BREEZHALER?

Medicinal ingredients: indacaterol (as acetate), glycopyrronium (as bromide) and mometasone furoate

Non-medicinal ingredients: carrageenan, hypromellose, lactose (as monohydrate), magnesium stearate, potassium chloride, purified water

ENERZAIR BREEZHALER comes in the following dosage forms:

Capsules for oral inhalation: 150 mcg / 50 mcg / 160 mcg

indacaterol (as acetate), glycopyrronium (as bromide) and mometasone furoate

Do not use ENERZAIR BREEZHALER if:

you are allergic to or have had an allergic reaction to:

- indacaterol
- glycopyrronium
- mometasone furoate
- any other ingredients in ENERZAIR BREEZHALER
- lactose or milk proteins

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ENERZAIR BREEZHALER. Talk about any health conditions or problems you may have, including if you:

- have heart problems such as:
 - an irregular or fast heartbeat (arrhythmia)
 - sensations that your heart has skipped a beat or added an extra beat (palpitations)
 - your heart muscle does not get enough blood (myocardial ischemia)
 - chest pain (angina)
 - an abnormal electrical signal called “prolongation of the QT interval”
- are taking similar medicines for your lung disease
- have low or high blood pressure
- if you have problems with your thyroid or adrenal glands
- if you have ever been told you have diabetes or high blood sugar
- have been taking other corticosteroids by mouth or inhalation
- have a fungal infection (thrush) in your mouth or throat
- have or have ever had pulmonary tuberculosis
- have chronic or untreated infections:
 - bacterial infection
 - viral infection
 - fungal infection
 - parasitic infection
 - herpes simplex infection of the eye
- if you suffer from seizures or fits
- if you have low potassium in your blood
- if you have severe liver problems
- if you have severe kidney problems
- if you have an eye problem called narrow-angle glaucoma
- if you have difficulty / pain passing urine. Talk to your doctor **right away** if you develop these signs or symptoms
- have a severe allergy to lactose or milk proteins

Other warnings you should know about:

General: When LABA medicines are used alone without an ICS, they increase the risk of hospitalization and death from asthma problems. ENERZAIR BREEZHALER contains both a LABA and ICS. Studies showed that when a LABA and ICS are used together, there is not a significant increased risk in hospitalizations and death from asthma problems.

ENERZAIR BREEZHALER does not relieve the sudden (acute) symptoms of asthma. You should always have a short-acting bronchodilator medicine (“rescue” inhaler) (such as salbutamol) with you to treat your sudden symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your doctor to have one prescribed for you. Use the medication as directed by your doctor.

Stop taking ENERZAIR BREEZHALER and get medical help right away if you have any of the following:

- tightness of the chest, coughing, wheezing or feeling breathlessness immediately after inhaling ENERZAIR BREEZHALER (signs of paradoxical bronchospasm)
- trouble breathing or swallowing, swelling of the tongue, lips or face, skin rash, itching and hives (signs of allergic reaction)

Do not stop taking ENERZAIR BREEZHALER without talking to your doctor. You should talk to your doctor **right away** if:

- there is a change in your symptoms such as more coughing, attacks of wheezing, chest tightness, or an unusual increase in the severity of the breathlessness
- you are using increasing amounts of your fast acting ‘reliever’ medicine

These could be warning signs that your condition may be getting worse.

Pregnancy: Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. Your doctor will discuss the potential risks of taking this medicine and whether you can use ENERZAIR BREEZHALER.

Breast-feeding: It is not known whether the ingredients of ENERZAIR BREEZHALER can pass into breast milk. If you are breast-feeding, check with your doctor before you use ENERZAIR BREEZHALER

Narrow-angle glaucoma: You should avoid getting the powder in the capsules into your eyes. If you do, it may cause:

- eye pain and/or discomfort,
- temporary blurring of vision, and/or
- coloured images in association with red eyes

If you have narrow-angle glaucoma, getting the powder in your eyes may cause it to get worse. It can also cause acute narrow-angle glaucoma. If you develop any of these symptoms, talk to your doctor **right away**.

Risk of Bone Fractures: When using medicines like ENERZAIR BREEZHALER for long-term treatment, you may be at risk of:

- breaking a bone
- osteoporosis (brittle bones)

Eye disorders: Medicines like ENERZAIR BREEZHALER can cause eye disorders:

- Cataracts: clouding of the lens in the eye, blurry vision, eye pain
- Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss
- Central serous chorioretinopathy (CSCR): blurry vision or other changes in vision.

Contact your healthcare professional if you experience blurry vision or other vision problems.

You should also have regular eye exams.

Chicken pox and measles: You should avoid exposure to chicken pox and measles, and notify your doctor if are exposed. This is important if you are taking any corticosteroid and your immune system is not functioning well (if you have difficulty in fighting an infection).

Monitoring and Laboratory Tests: your doctor may monitor you and perform the tests to check your:

- potassium levels in your blood. Low levels of potassium have been seen in people taking beta-agonist therapies, which may increase your risk of heart arrhythmia.
- blood sugar levels. High blood glucose levels have been seen in people taking beta-agonist medicines. This is important if you are diabetic.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ENERZAIR BREEZHALER:

- medicines that prolong QT interval (your hearts electrical signal) including medicines used in the treatment of depression (e.g. tricyclic antidepressants, monoamine oxidase inhibitors)
- any medicines that may be similar to ENERZAIR BREEZHALER (contain similar ingredients) used to treat your lung disease. Using these together with ENERZAIR BREEZHALER may increase the risk of experiencing possible side effects
- atropine or other medications that contain a short-acting, or a long-acting muscarinic antagonist (LAMA) (such as ipratropium, tiotropium, aclidinium, umeclidinium)
- medicines that decrease the level of potassium in your blood. These include:
 - diuretics (also known as “water pills”) and are used to treat high blood pressure, e.g. hydrochlorothiazide)
 - other bronchodilators such as methylxanthines used for breathing problems (e.g. theophylline) or steroids (e.g. prednisolone)
- beta blockers used to treat high blood pressure or other heart problems (e.g. propranolol) or to treat glaucoma (e.g. timolol)
- medicine used to treat fungal infections (e.g., ketoconazole or itraconazole)
- medicine used to treat HIV infection (e.g., ritonavir, nelfinavir or cobicistat)

How to take ENERZAIR BREEZHALER:

Important:

- **The capsules are for oral inhalation only. DO NOT SWALLOW.**
- ENERZAIR BREEZHALER does not relieve sudden symptoms of asthma. Always have a rescue inhaler with you to treat sudden symptoms. If you do not have a rescue inhaler, call your doctor to have one prescribed for you.
- Always use this medicine exactly as your doctor has told you. Do not stop using it unless your doctor tells you to.
- It is important that you continue to take ENERZAIR BREEZHALER regularly even if

you feel fine and do not have any symptoms

- If your asthma is not getting better or it gets worse after you have started using ENERZAIR BREEZHALER, talk to your doctor

Usual dose:

Adults: Inhale the contents of 1 capsule once a day at about the same time each day. Rinse your mouth with water after each inhalation. **Do not** swallow the water.

Instructions for use

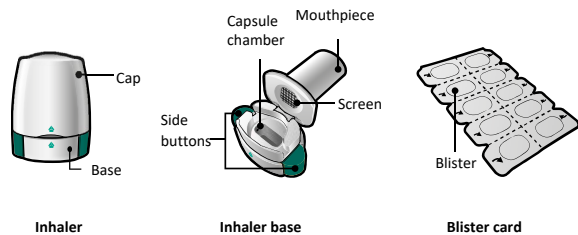
This part of the leaflet explains how to use and care for your ENERZAIR BREEZHALER inhaler. Please read carefully and follow these instructions.

Please read the full **Instructions for Use** before using the ENERZAIR BREEZHALER.

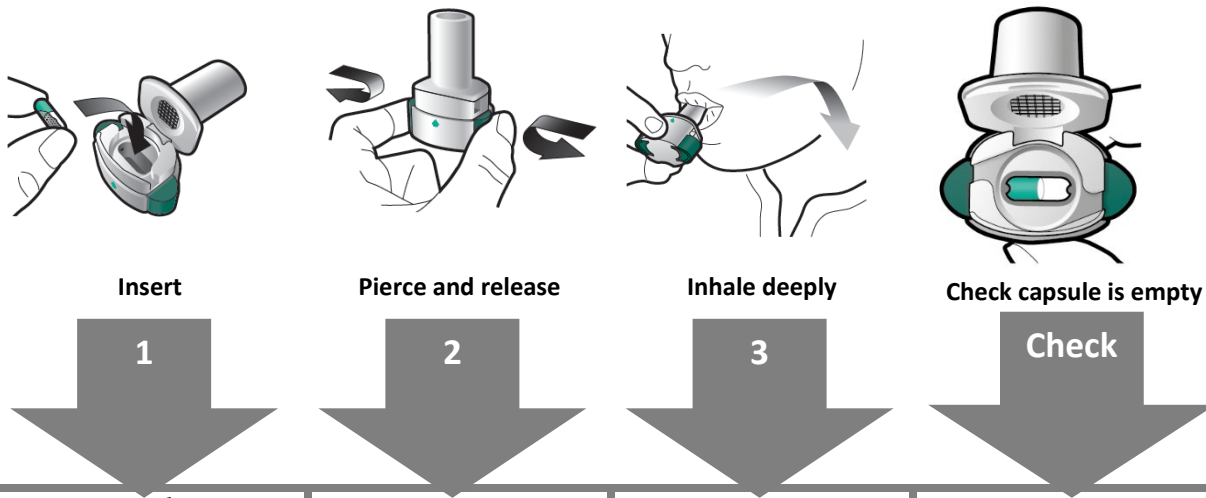
If you have any questions, ask your doctor or pharmacist.

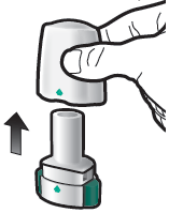
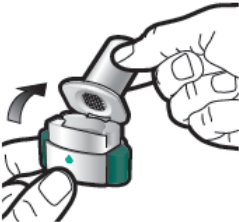
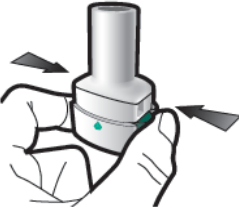





Your ENERZAIR BREEZHALER Inhaler pack contains:

- 1 inhaler device
- Blister cards containing the ENERZAIR BREEZHALER capsules to be used in the inhaler

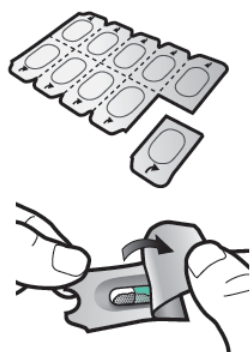


Steps:



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|  <p>Step 1a: Pull off cap</p>  |  <p>Step 2a: Pierce capsule once</p> <p>Hold the inhaler upright.</p> <p>Pierce capsule by firmly pressing both side buttons at the same time.</p> <p>You should hear a noise as the capsule is pierced.</p> <p><u>Only pierce the capsule once.</u></p> |  <p>Step 3a: Breathe out fully</p> <p><u>Do not blow into the inhaler.</u></p>  |  <p>Check capsule is empty</p> <p>Open the inhaler to see if any powder is left in the capsule.</p> <p>If there is powder left in the capsule:</p> <ul style="list-style-type: none"> • Close the inhaler. • Repeat steps 3a to 3d. <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Powder remaining</p> </div> <div style="text-align: center;">  <p>Empty</p> </div> </div> |
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**Step 1b:
Open inhaler**



**Step 1c:
Remove capsule**

Separate one of the blisters from the blister card.

Peel open the blister and remove the capsule.

Do not push the capsule through the foil.

Do not swallow the capsule.



**Step 2b:
Release side buttons**

**Step 3b:
Inhale medicine deeply**

Hold the inhaler as shown in the picture.

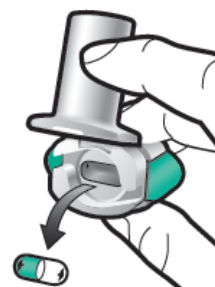
Place the mouthpiece in your mouth and close your lips firmly around it.

Do not press the side buttons.

Breathe in quickly and as deeply as you can.

During inhalation you will hear a whirring noise.

You may taste the medicine as you inhale.



Remove empty capsule

Put the empty capsule in your household waste.

Close the inhaler and replace the cap.



**Step 3c:
Hold breath**

Hold your breath for up to 5 seconds.

**Step 3d :
Rinse mouth**

Rinse your mouth with water after each dose and spit it out.



Step 1d:
Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:
Close inhaler

Important Information

- ENERZAIR BREEZHALER capsules must always be stored in the blister card and only removed immediately before use.
- Do not push the capsule through the foil to remove it from the blister.
- Do not swallow the capsule.
- Do not use the ENERZAIR BREEZHALER capsules with any other inhaler.
- Do not use the ENERZAIR BREEZHALER inhaler to take any other capsule medicine.
- Never place the capsule into your mouth or the mouthpiece of the inhaler.
- Do not press the side buttons more than once.
- 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.

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| <p>Frequently Asked Questions</p> <p>Why didn't the inhaler make a noise when I inhaled? The capsule may be stuck in the capsule chamber. If this happens, carefully loosen the capsule by tapping the base of the inhaler. Inhale the medicine again by repeating steps 3a to 3d.</p> <p>What should I do if there is powder left inside the capsule? You have not received enough of your medicine. Close the inhaler and repeat steps 3a to 3d.</p> <p>I coughed after inhaling – does this matter? This may happen. As long as the capsule is empty you have received enough of your medicine.</p> <p>I felt small pieces of the capsule on my tongue – does this matter? This can happen. It is not harmful. The chances of the capsule breaking into small pieces will be increased if the capsule is pierced more than once.</p> | <p>Cleaning the inhaler</p> <p>Wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry. Never wash your inhaler with water.</p> <hr/> <p>Disposing of the inhaler after use</p> <p>Each inhaler should be disposed of after all capsules have been used. Ask your pharmacist how to dispose of medicines and inhalers that are no longer required.</p> |
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Overdose:

If you think you, or a person you are caring for, have taken too much ENERZAIR BREEZHALER , contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Symptoms of an overdose include:

- fast heart rate
- feeling shaky
- sensations that your heart has skipped a beat or added an extra beat
- an irregular or fast heartbeat
- headache
- nausea
- vomiting
- feeling drowsy

Missed Dose:

If you forget to inhale a dose, inhale the dose as soon as possible. Then inhale the next dose at the usual time. **Do not** inhale 2 doses (i.e. 2 capsules) on the same day.

What are possible side effects from using ENERZAIR BREEZHALER?

These are not all the possible side effects you may have when taking ENERZAIR BREEZHALER. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- a frequent urge to urinate and pain or burning when urinating (signs of urinary tract infection)
- headache
- sore throat or pain and irritation in the back of the mouth and throat
- cough
- hoarseness and changes to your voice
- diarrhea, abdominal cramps, nausea, and vomiting (gastroenteritis)
- dry mouth
- rash
- muscle spasm
- pain in muscles, bones or joints
- fever
- itchy skin

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| COMMON | | | |
| Allergic Reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat. | | | X |
| Thrush (yeast infection): white patches in the mouth and tongue, sore throat | | X | |
| Fast heart beat | | X | |
| UNCOMMON | | | |
| Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue | | X | |
| Dysuria: difficulty and pain when passing urine | | X | |
| UNKNOWN | | | |
| Paradoxical Bronchospasm (worsening of symptoms related to breathing): Tightness of the chest associated with coughing, sudden worsening of shortness of breath and wheezing right | | | X |

| | | | |
|---|--|---|--|
| after inhaling ENERZAIR BREEZHALER | | | |
| Glaucoma: increased pressure in your eyes, eye and head pain, swelling or redness in or around the eye, and changes in vision, hazy or blurred vision, sudden sight loss | | X | |
| Cataract: clouding of the lens in the eye, blurry vision, dim vision and/or eye pain | | X | |
| Central Serous Chorioretinopathy (CSCR): distorted vision/blurred vision | | X | |
| Irregular heartbeat | | X | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep this medicine out of the sight and reach of children.
- At room temperature (15-30°C) in the original package to protect from moisture and light. Remove capsules from the package only when ready to use.
- Do not use after the expiry date shown on the box.

If you want more information about ENERZAIR BREEZHALER:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug->

[product-database.html](#)); the manufacturer's website www.novartis.ca, the distributor's website www.valeopharma.com or by calling 1-855-694-0151.

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