

PART III: CONSUMER INFORMATIONPr **SEEBRI® BREEZHALER®**

Glycopyrronium inhalation powder hard capsules

This leaflet is part III of a three-part "Product Monograph" published when SEEBRI® BREEZHALER® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SEEBRI® BREEZHALER®. Contact your doctor, nurse, or pharmacist if you have any questions about the drug.

PLEASE READ THIS INFORMATION CAREFULLY AND COMPLETELY BEFORE YOU USE SEEBRI® BREEZHALER® EVEN IF YOU HAVE JUST REFILLED YOUR PRESCRIPTION, SINCE SOME INFORMATION MAY HAVE CHANGED.

ABOUT THIS MEDICATION**What the medication is used for:**

SEEBRI® BREEZHALER® is used long term once daily to treat breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD).

It is not for treating sudden, severe symptoms of COPD.

What it does:

SEEBRI® BREEZHALER® contains glycopyrronium bromide which belongs to a group of medicines called bronchodilators. In COPD the muscles around the airways tighten, making breathing difficult. SEEBRI® BREEZHALER® blocks tightening of these muscles in the lungs, making it easier for air to get in and out of the lungs. When you inhale it, it helps you breathe more easily.

When it should not be used:

Do not use SEEBRI® BREEZHALER®:

- If you have a severe allergy to glycopyrronium bromide or any other component of SEEBRI® BREEZHALER®. Ask your doctor, nurse, or pharmacist if you are unsure.
- To treat sudden, severe symptoms of COPD such as shortness of breath or wheezing.
- If you have a lactose or severe milk protein allergy as this product contains lactose.
- SEEBRI® BREEZHALER® should not be used in children. COPD does not occur in children.
- If you are younger than 18 years of age.

What the medicinal ingredient is:

glycopyrronium bromide.

What the nonmedicinal ingredients are:

Lactose monohydrate and magnesium stearate.

The capsule shell contains hypromellose, purified water, carrageenan, potassium chloride and FDC Yellow 6 (110 Sunset Yellow FCF).

What dosage forms it comes in:

Clear Orange capsules for oral **inhalation**. Each capsule contains 63 mcg of glycopyrronium bromide equivalent to 50 mcg of glycopyrronium.

Each pack includes an inhaler and capsules (in blister strips) that contain the medicine as inhalation powder.

WARNINGS AND PRECAUTIONS

BEFORE using SEEBRI® BREEZHALER® talk to your doctor, nurse, or pharmacist if you:

- are pregnant or planning to become pregnant;
- are a breastfeeding mother;
- have heart problems, such as rapid or irregular heart beat or abnormal electrical signal called "prolongation of the QT interval";
- are taking any medications including eye drops, this includes medications you can buy without prescription;
- have an enlarged prostate, problems passing urine or painful urination;
- have eye problems, such as glaucoma or eye pain, blurred vision, see halos around lights or coloured images;
- have any allergies to food or drugs;
- are allergic to lactose (milk sugar);
- have problems with your kidneys.

These capsules are intended for inhalation only.

DO NOT SWALLOW.

SEEBRI® BREEZHALER® should not be used more frequently than once daily. Do not exceed the prescribed dose.

This medication has been prescribed for you and should not be given to other people.

Avoid getting the drug powder into your eyes. This may result in eye pain and/or discomfort, temporary blurring of vision, and/or coloured images in association with red eyes. These may be signs of acute narrow-angle glaucoma. Should any of these symptoms develop, consult a doctor immediately.

Remember to tell any other doctor, nurse, dentist or pharmacist you consult that you are taking this medication.

Driving and Using Machines:

The occurrence of dizziness or blurred vision may influence the ability to drive and use machinery.

During the treatment with SEEBRI® BREEZHALER®, tell your doctor immediately if you experience any of the following symptoms:

- If you experience a tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation of SEEBRI® BREEZHALER® (signs of bronchospasm)

- If you experience difficulties in breathing or swallowing, swelling of tongue, lips and face, hives or itching, skin rash (signs of hypersensitivity reaction). Do not use **SEEBRI® BREEZHALER®** again before speaking with your doctor.
- If your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen during your treatment stop taking **SEEBRI® BREEZHALER®** and tell your doctor immediately
- if you experience eye pain or discomfort, temporary blurring of vision, visual halos or colored images in association with red eyes; these may be signs of an acute attack of narrow-angle glaucoma.

SEEBRI® BREEZHALER® does not relieve sudden symptoms of COPD. Always have a short-acting bronchodilator medicine with you to treat acute symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your healthcare provider to have one prescribed for you.

Get emergency medical care if:

- **breathing problems worsen quickly**
- **you use your short-acting bronchodilator medicine, but it does not relieve your breathing problems**

Ask your doctor or pharmacist for advice before taking any additional medicine.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor, nurse, or a pharmacist if you are taking or have recently taken any other medicines, including prescription and non-prescription drugs, eye drops, vitamins, and herbal supplements.

It's not recommended to use **SEEBRI® BREEZHALER®** with anticholinergics. Especially tell your doctor if you take any of the following as these medicines may interact with **SEEBRI® BREEZHALER®**:

- atropine or other anticholinergics (ipratropium, oxitropium, tiotropium, etc.).

PROPER USE OF THIS MEDICATION

Always use this medicine exactly as your doctor, nurse, or pharmacist has told you. Check with your doctor, nurse, or pharmacist if you are not sure.

You can inhale **SEEBRI® BREEZHALER®** before or after food or drink.

Usual adult dose:

Inhale the contents of one capsule through the mouth each day, everyday at the same time.

Use **SEEBRI® BREEZHALER®** even when you have no breathing problems or other symptoms of COPD.

You only need to inhale once a day to help you breathe easier because **SEEBRI® BREEZHALER®** lasts for 24 hours. Taking **SEEBRI® BREEZHALER®** at the same time each day will also

help you to remember to use it.

How to inhale **SEEBRI® BREEZHALER®**

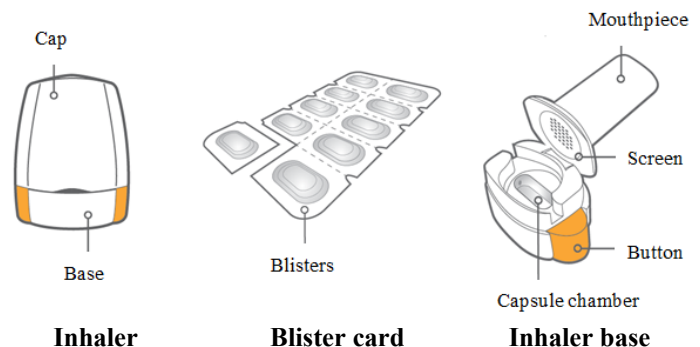
- Only use the inhaler contained in this pack (**SEEBRI® BREEZHALER®** inhaler) to inhale the powder in a capsule. **Do not swallow the capsules.**
- Capsules should always be stored in the blister strip and only removed immediately before use.
- When you start a new pack, use the new **SEEBRI® BREEZHALER®** inhaler supplied in this new pack. Dispose of each inhaler after 30 days of use.

How long to continue to take **SEEBRI® BREEZHALER®**

- Keep using **SEEBRI® BREEZHALER®** for as long as your doctor tells you.
- COPD is a long-term disease and you should use **SEEBRI® BREEZHALER®** every day and not only when you have breathing problems or other symptoms of COPD.
- If you have questions about how long to take **SEEBRI® BREEZHALER®**, talk to your doctor or pharmacist.

Each one of your **SEEBRI® BREEZHALER®** pack contains

- One **SEEBRI® BREEZHALER®** inhaler consisting of a cap and a base.
- one or more blisters containing **SEEBRI® BREEZHALER®** capsules to be used in the inhaler.



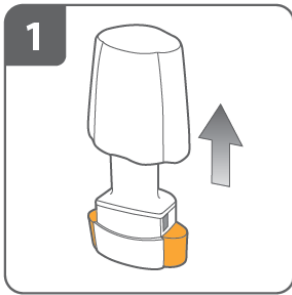
Only use the **SEEBRI® BREEZHALER®** inhaler contained in this pack to inhale the powder in the capsule.

Do not use **SEEBRI® BREEZHALER®** capsules with any other inhaler. Do not use **SEEBRI® BREEZHALER®** inhaler to take any other capsule medicine.

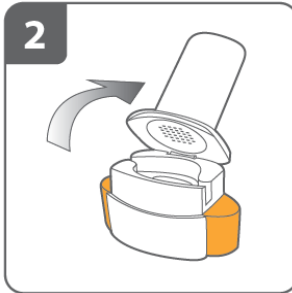
Dispose of each inhaler after 30 days. Ask your pharmacist how to dispose of medicines and inhalers no longer required.

Do not swallow **SEEBRI® BREEZHALER® capsules.** The powder in the capsules is for you to inhale.

How to use your SEEBRI® BREEZHALER® inhaler:

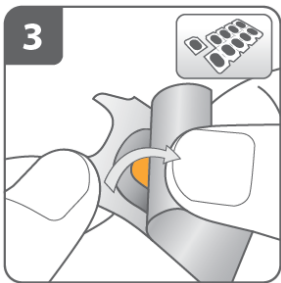


Pull off cap.



Open inhaler:

Hold the base of the inhaler firmly and tilt the mouthpiece to open the inhaler.

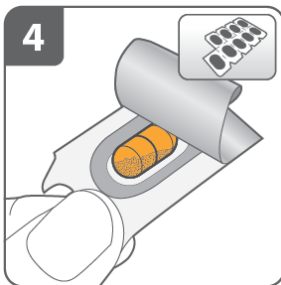


Prepare capsule:

Separate one of the blisters from the blister card by tearing along the perforation.

Take one blister and peel away the protective backing to expose the capsule.

Do not push the capsule through the foil.

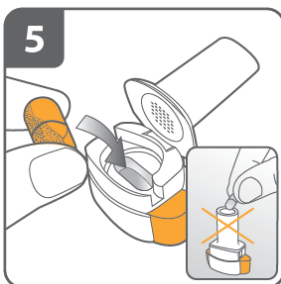


Remove one SEEBRI® BREEZHALER® capsule:

Capsules should always be stored in the blister and only removed immediately before use.

With dry hands, remove the capsule from the blister.

Do not swallow the SEEBRI® BREEZHALER® capsule.



Insert capsule:

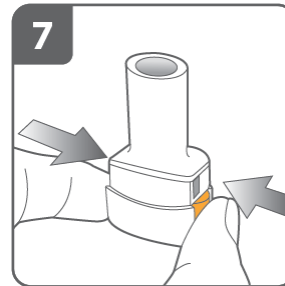
Place the capsule into the capsule chamber.

Never place a capsule directly into the mouthpiece.



Close the inhaler:

Close the inhaler fully. You should hear a 'click' as it fully closes.

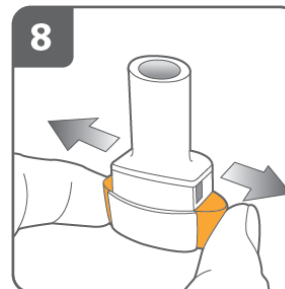


Pierce the capsule:

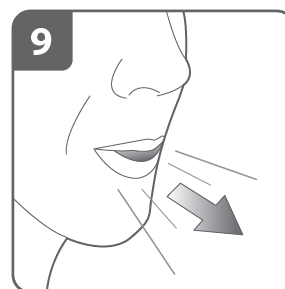
Hold the inhaler upright with the mouthpiece pointing up.

Press both buttons together firmly at the same time. You should hear a 'click' as the capsule is being pierced.

Do not press the piercing buttons more than once.



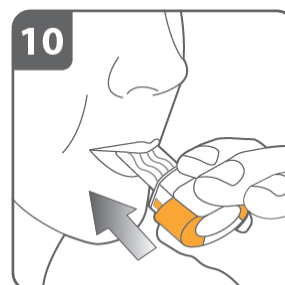
Release the buttons fully.



Breathe out:

Before placing the mouthpiece in your mouth, breathe out fully.

Never blow into the mouthpiece.

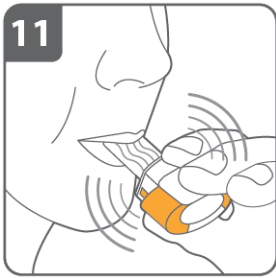


Inhale the medicine:

Before breathing in:

- Hold the inhaler as shown in the picture with the buttons to the left and right (not up and down).
- Place the mouthpiece in your mouth and close your lips firmly around the mouthpiece.

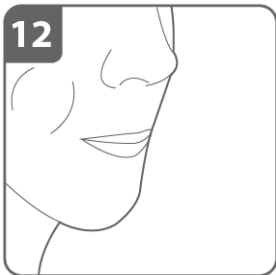
Breathe in rapidly but steadily, as deeply as you can. **Do not press the piercing buttons.**



Note:

As you breathe in through the inhaler, the capsule spins around in the chamber and you should hear a whirring noise. You will experience a sweet taste as the medicine goes into your lungs.

If you do not hear a whirring noise, the capsule may be stuck in the capsule chamber. If this occurs, open the inhaler and carefully loosen the capsule by tapping the base of the inhaler. **Do not press the piercing buttons to loosen the capsule.** Repeat steps 9 and 10 if necessary.

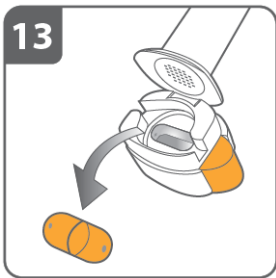


Hold breath:

Continue to hold your breath for at least 5-10 seconds or as long as comfortably possible while removing the inhaler from your mouth. Then breathe out.

Open the inhaler to see if any powder is left in the capsule. **If there is powder left in the capsule**, close the inhaler and repeat steps 9 to 12. Most people are able to empty the capsule with one or two inhalations.

Some people occasionally cough briefly soon after inhaling the medicine. If you do, don't worry, as long as the capsule is empty, you have received the full dose.



Remove capsule:

After you have finished taking your daily dose of SEEBRI® BREEZHALER®, open the mouthpiece again, remove the empty capsule by tipping it out of the capsule chamber, and discard it. Close the inhaler and replace the cap.

Do not store the capsules in the SEEBRI® BREEZHALER® inhaler.

REMEMBER:

- **Do not swallow SEEBRI® BREEZHALER® capsules.**
- **Only use the SEEBRI® BREEZHALER® inhaler contained in this pack.**
- SEEBRI® BREEZHALER® capsules must always be stored in the blister, and only removed immediately before use.
- Never place a SEEBRI® BREEZHALER® capsule directly into the mouthpiece of the SEEBRI® BREEZHALER® inhaler.

- Do not press the piercing buttons more than once.
- Never blow into the mouthpiece of the SEEBRI® BREEZHALER® inhaler.
- Always release the push buttons before inhalation.
- Never wash the SEEBRI® BREEZHALER® inhaler with water. Keep it dry. See below **“How to clean your inhaler”**.
- Never take the SEEBRI® BREEZHALER® inhaler apart.
- Always keep the SEEBRI® BREEZHALER® inhaler and SEEBRI® BREEZHALER® capsules in a dry place.
- Avoid getting the drug powder in your eyes.

Additional information

Occasionally, very small pieces of the capsule can get past the screen and enter your mouth. If this happens, you may be able to feel these pieces on your tongue. It is not harmful if these pieces are swallowed or inhaled. The chances of the capsule shattering will be increased if the capsule is pierced more than once (step 7).

How to clean your inhaler

Never wash your inhaler with water. If you want to clean your inhaler, wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry.

Overdose:

If you think you have inhaled too much SEEBRI® BREEZHALER®, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to inhale a dose, inhale one as soon as possible but do not inhale two doses on the same day. Then inhale the next dose as usual.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients using SEEBRI® BREEZHALER® may experience side effects, although not everybody gets them.

Side effects may include:

- Upset stomach, indigestion
- Pain in extremities (e.g. arms or legs)
- Feeling of pressure or pain in the cheeks and forehead (possible symptoms of sinus congestion)
- Dry mouth
- Nausea, vomiting, diarrhea and abdominal pain (possible symptoms of gastroenteritis)
- Difficulty sleeping

- Symptoms of common cold (runny or stuffy nose, cough, sore throat, sneezing)
- Pain in muscles, bones or joints
- Cavities
- Rash
- Tiredness
- Weakness
- Throat irritation
- Nose bleeds
- Tingling or numbness
- Itching
- Voice alteration (hoarseness)

Some elderly patients above 75 years of age have also experienced headache and urinary tract infection.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Uncommon	New occurrence of irregular heart beat			✓
	Increased blood sugar: Frequent urination, thirst, and hunger		✓	
	Difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips		✓	
	Glaucoma: New or worsened pressure in your eyes, eye pain or discomfort, blurred vision, seeing halos of bright colours around lights, red eyes			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Unknown	Paradoxical Bronchospasm: Tightness of the chest associated with coughing, wheezing, or breathlessness immediately after inhalation of SEEBRI® BREEZHALER®			✓
	Allergic Reaction: rash, hives, swelling of the face, mouth, lips, throat and tongue, difficulty swallowing or breathing			✓

This is not a complete list of side effects. For any unexpected effects while taking SEEBRI® BREEZHALER®, contact your doctor, nurse, or pharmacist.

HOW TO STORE IT

Do not use after the expiry date shown on the box.

Store SEEBRI® BREEZHALER® at room temperature between 15 to 25°C.

Store the capsules in the original package in a dry place in order to protect from heat and moisture. Do not remove capsules from the blister pack until immediately before use.

Do not use this medicine if you notice that the pack is damaged or show signs of tampering.

Each inhaler should be disposed of after 30 days of use.

Keep out of sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the product monograph, prepared for health professionals can be found at: <http://www.novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

This leaflet was prepared by:
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