

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrULTIBRO® BREEZHALER®

Indacaterol (as maleate) / glycopyrronium (as bromide) inhalation powder hard capsules

Read this carefully before you start taking **ULTIBRO® 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 **ULTIBRO BREEZHALER**.

Serious Warnings and Precautions

ASTHMA-RELATED DEATH

ULTIBRO BREEZHALER should only be used to treat COPD.

ULTIBRO BREEZHALER should not be used to treat asthma.

Long-acting beta₂-agonist (LABA) medicines may increase the chance of death from asthma. In a large asthma study, more patients who used another LABA medicine (salmeterol) died from asthma compared with patients who did not use that LABA medicine. This finding may also apply to **ULTIBRO BREEZHALER**.

What is **ULTIBRO BREEZHALER** used for?

ULTIBRO BREEZHALER is used in adults as a long term, once daily maintenance treatment. It can make breathing easier for people who experience breathing difficulties due to a lung disease called Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema. It is also used to reduce the likelihood of “flare-ups” in people with COPD who have previously had these events. A “flare-up” is when your condition is getting worse.

If you are a smoker, it is important to quit smoking. This will help decrease the symptoms of COPD and potentially increase your lifespan.

How does **ULTIBRO BREEZHALER** work?

ULTIBRO BREEZHALER contains two medicinal ingredients:

- Indacaterol is a long-acting beta₂ agonist (LABA)
- Glycopyrronium is a long-acting muscarinic antagonist (LAMA)

Both ingredients belong to a group of medicines called bronchodilators. They help to open and relax the muscles of the airways. This allows more air to get in and out of the lungs. This makes it easier for patients with COPD to breathe and helps prevent shortness of breath and wheezing.

This medicine does not cure COPD but helps to control it. It is therefore important that you continue to take **ULTIBRO BREEZHALER** regularly even if you feel fine.

What are the ingredients in ULTIBRO BREEZHALER?

Medicinal ingredients: Indacaterol maleate and glycopyrronium bromide

Non-medicinal ingredients: Carrageenan, FD&C Yellow 5/Tartrazine, hypromellose, lactose monohydrate (which contains milk proteins), magnesium stearate, potassium chloride, purified water.

ULTIBRO BREEZHALER comes in the following dosage forms:

Dry powder capsules for oral **inhalation** delivered by the BREEZHALER inhaler. Each capsule contains 110 mcg indacaterol and 50 mcg glycopyrronium.

Do not use ULTIBRO BREEZHALER:

- if you are allergic to indacaterol maleate, glycopyrronium bromide or any of the non-medicinal ingredients in ULTIBRO BREEZHALER (see **What are the ingredients in ULTIBRO BREEZHALER?**)
- to treat sudden, severe symptoms of COPD such as sudden shortness of breath or wheezing. Always have a rescue inhaler with you to treat sudden symptoms (“flare ups”). If you do not have a rescue inhaler, ask your healthcare professional to prescribe one for you.
- to treat asthma.
- if you have a lactose or severe milk protein allergy. ULTIBRO BREEZHALER contains lactose.

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

- are pregnant or planning to become pregnant
- are breastfeeding or plan to breastfeed
- have heart problems, such as:
 - heart disease
 - rapid or irregular heart beat or any problems with how your heart beats
 - a condition called “ QT prolongation”
- have high blood pressure
- have had seizures or fits
- have thyroid problems
- have low levels of potassium in your blood
- have diabetes
- are taking similar medicines for your lung disease
- have liver or kidney problems
- have eye problems, such as increased pressure in the eye or glaucoma
- have prostate, bladder problems, or problems passing urine

Other warnings you should know about:

Eye Problems: Avoid getting ULTIBRO BREEZHALER powder into your eyes. This may cause eye pain, discomfort, temporary blurring of vision, and/or coloured images in association with red eyes. These may

be signs of acute narrow-angle glaucoma (eye pain caused by increased pressure in the eyes). If you develop any of these symptoms talk to your healthcare professional right away.

Driving and Using Machines: ULTIBRO BREEZHALER can cause dizziness or blurred vision. You should not drive or operate machinery if this occurs.

COPD Flare-Ups: ULTIBRO BREEZHALER does not relieve sudden symptoms of COPD. Always have a rescue inhaler (short-acting bronchodilator medicine such as salbutamol) with you to treat acute symptoms. If you do not have rescue inhaler, talk to your healthcare professional.

Talk to your healthcare professional immediately if you have any of the following symptoms. They could be signs that you are having a COPD flare-up or that your COPD is worsening:

- unusual increase in the severity of breathlessness, cough, wheezing, or fatigue
- unusual colour, amount or thickness of mucus
- tightness in the chest or symptoms of a cold
- you need to use your rescue inhaler more often than usual
- your rescue inhaler does not work as well to relieve your symptoms

Monitoring and Laboratory Tests: ULTIBRO BREEZHALER can cause abnormal blood test results such as low blood levels of potassium and high blood sugar. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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

The following may interact with ULTIBRO BREEZHALER:

- medicines used in the treatment of depression or sad mood, such as tricyclic antidepressants, monoamine oxidase inhibitors
- other medications (including combinations) that contain a long-acting beta agonist (LABA), such as formoterol, salmeterol, indacaterol, vilanterol, olodaterol
- other medications that contain a short-acting, or a long-acting muscarinic antagonist (LAMA), such as ipratropium, tiotropium, glycopyrronium, aclidinium, umeclidinium
- medicines that lower the level of potassium in your blood. These include diuretics (also known as “water tablets”) used to treat high blood pressure, such as hydrochlorothiazide, other bronchodilators, such as methylxanthines used for breathing problems (e.g. theophylline) or steroids, such as prednisolone
- Beta-blockers used in the treatment of high blood pressure or other heart problems, such as propranolol or in the treatment of glaucoma, such as timolol
- ketoconazole, used to treat fungal infections
- ritonavir, used to treat HIV and AIDS
- erythromycin, used to treat bacterial infections
- verapamil, used to treat high blood pressure, severe chest pain, irregular heartbeat

How to take ULTIBRO BREEZHALER:

- Always use ULTIBRO BREEZHALER exactly as your healthcare professional has told you. Do not take more than once a day. Talk to your healthcare professional if you are not sure.

- The contents of the capsule must be inhaled once daily through the mouthpiece of the ULTIBRO BREEZHALER inhalation device only. **Do NOT swallow the capsule.** The ULTIBRO BREEZHALER inhaler is especially designed for ULTIBRO BREEZHALER capsules and must **not** be used with any other capsules. Likewise, you should not take your ULTIBRO BREEZHALER capsules with any inhalation device other than the ULTIBRO BREEZHALER inhaler.
- When you start a new pack, use the ULTIBRO BREEZHALER inhaler supplied in the new pack. Dispose of each inhaler after 30 days of use.
- You can inhale ULTIBRO BREEZHALER before or after food or drink.
- Store the ULTIBRO BREEZHALER capsules in the blister strip until immediately before use.
- Before starting your treatment with ULTIBRO BREEZHALER, make sure that you are completely familiar with the use and proper care of the ULTIBRO BREEZHALER inhaler. See the **Instructions for Use** for complete information.
- It is important that you continue to take ULTIBRO BREEZHALER regularly even if you feel fine and do not have any symptoms.

If you have any questions about ULTIBRO BREEZHALER or the ULTIBRO BREEZHALER inhaler, talk to your healthcare professional.

Usual dose:

Inhale the contents of one ULTIBRO BREEZHALER capsule once daily, preferably at the same time each day.

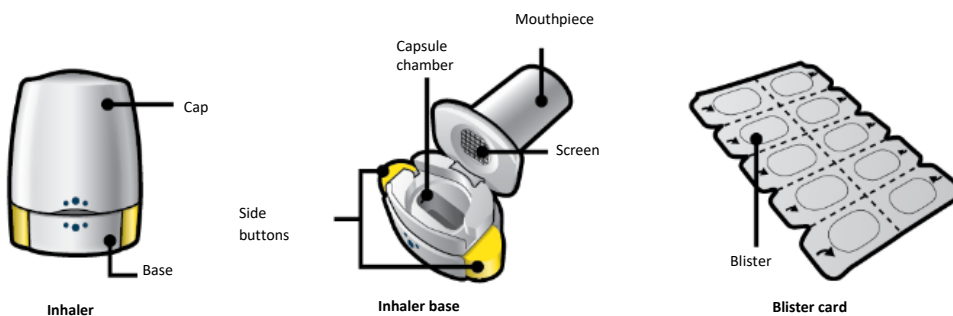
Instructions for use:

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

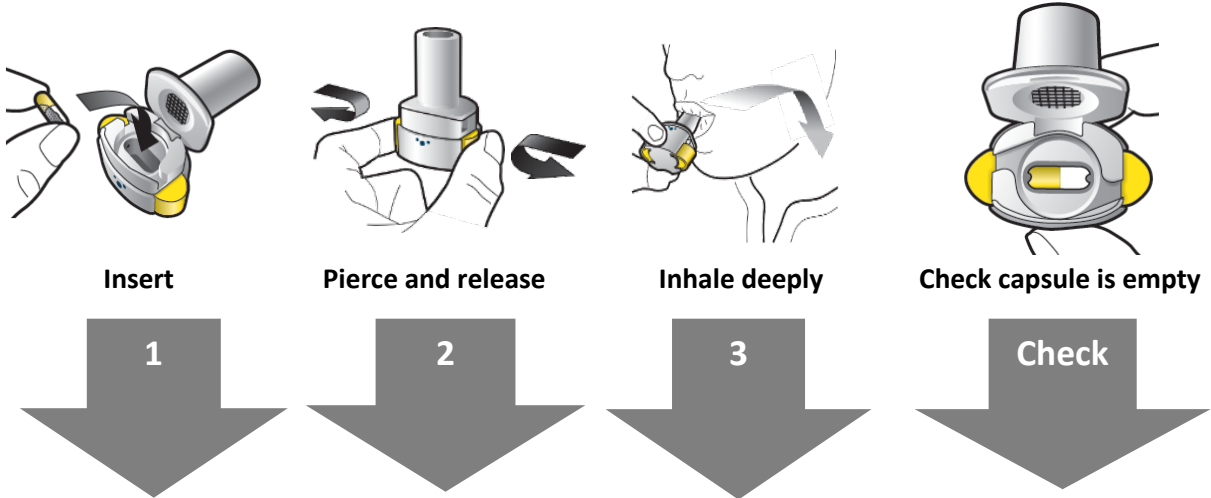
If you have any questions, ask your healthcare professional.

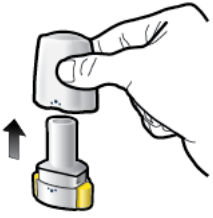



Your ULTIBRO BREEZHALER Inhaler pack contains:

- One ULTIBRO BREEZHALER inhaler
- Blister cards containing ULTIBRO BREEZHALER capsules to be used in the inhaler



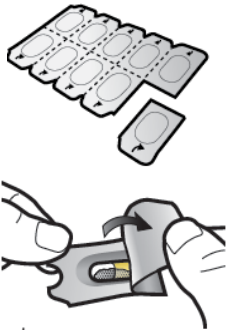
Please read the full **Instructions for Use** before using the ULTIBRO BREEZHALER inhaler.



 <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>Step 3a: Breathe out fully <u>Do not blow into the inhaler.</u></p>	 <p>Check capsule is empty Open the inhaler to see if any powder is left in the capsule.</p>
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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

You should hear a noise as the capsule is pierced.

Only pierce the capsule once.



**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.

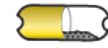


**Step 3c:
Hold breath**

Hold your breath for up to 5 seconds or for as long as you comfortably can.

If there is powder left in the capsule:

- Close the inhaler.
- Repeat steps 3a to 3c.



Powder remaining



Empty



Remove empty capsule

Put the empty capsule in your household waste.

Close the inhaler and replace the cap.

capsule.



Step 1d:

Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:

Close inhaler

Important Information

- ULTIBRO 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 ULTIBRO BREEZHALER capsules with any other inhaler.
- Do not use the ULTIBRO 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.
- Never take the inhaler apart.

<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 3c.</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 3c.</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 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> <p>Disposing of the inhaler after use 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 inhaled too much ULTIBRO BREEZHALER, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

If you accidentally take a larger dose of ULTIBRO BREEZHALER you may feel shaky, have a headache, or feel like your heart is beating faster than usual. Talk to your healthcare professional right away if this occurs.

Missed Dose:

If you miss or forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the next dose at your regular time. Do not take two doses on the same day.

What are possible side effects from using ULTIBRO BREEZHALER?

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

Side effects may include:

- feeling of pressure or pain in the cheeks and forehead (possible symptoms of sinusitis, inflammation of the sinuses)
- runny or stuffy nose, sneezing
- dizziness
- headache
- cough
- sore throat/or mouth
- upset stomach, indigestion
- nausea, vomiting, diarrhea, stomach pain
- cavities
- pain in muscles, bones or joints, arms or legs
- fever
- trouble falling asleep (insomnia)
- tingling or numbness
- nose bleeds
- dry mouth
- skin itching/rash
- muscle spasm
- tiredness
- swollen hands, ankles and feet
- hoarse voice

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: difficulties in breathing or swallowing, swelling of tongue, lips, mouth, throat and face, skin rash, itching, hives			✓
High blood sugar: increased thirst, frequent urination, increased appetite with weight loss, tiredness		✓	
Urinary retention: difficulty and pain when passing urine, urinating frequently, urination in a weak stream or drips		✓	
Bladder Infection: painful and frequent urination, increased need to urinate, pain in the lower pelvis or back, cloudy or bloody urine,		✓	

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	
burning sensation when passing urine			
UNCOMMON			
Heart problems: crushing chest pain with increased sweating			✓
Heart palpitations: unusually fast or irregular heartbeat	✓		
Chest pain		✓	
Paradoxical bronchospasm (sudden narrowing of the airways after taking ULTIBRO BREEZHALER): tightness of the chest associated with coughing, shortness of breath and wheezing right after inhaling ULTIBRO BREEZHALER			✓
Eye problems: new or worsened pressure in your eyes, eye pain or discomfort, temporary blurred vision, seeing halos of bright colours around lights, red eyes			✓
Gastroenteritis (inflammation of the stomach and intestines): abdominal pain, diarrhea, results in nausea, vomiting		✓	
NOT KNOWN			
Low levels of potassium in the blood: irregular heartbeats, muscle weakness and spasms, generally feeling unwell		✓	
Angioedema (swelling of the tissues under the skin): difficulty breathing, swelling of the tongue, lips, face and throat, hands and feet, genitals, swelling of the digestive tract causing diarrhea, nausea, vomiting			✓

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:

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

Store ULTIBRO 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 light, heat and moisture. Do not remove capsules from blister pack until immediately before use.

Keep this medicine out of the reach and sight of children

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

Do not use this medicine if you notice that the pack is damaged or show signs of tampering. Ask your pharmacist how to dispose of medicines you no longer use.

If you want more information about ULTIBRO 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.covispharma.com or by calling 1-833-523-3009.

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