

PART III: CONSUMER INFORMATION**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 **ULTIBRO BREEZHALER**. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about **ULTIBRO BREEZHALER**.

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

ULTIBRO BREEZHALER is used long term once daily to treat breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD). It is also used to reduce the likelihood of “flare-ups” in people with COPD who have previously had these events.

In COPD, a “flare-up” is when your condition is getting worse. You will know you are having a “flare-up” if two of the following symptoms get worse for more than two days:

- 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.

ULTIBRO BREEZHALER is not for treating sudden, severe symptoms of COPD.

What it does:

ULTIBRO BREEZHALER contains two active substances called indacaterol and glycopyrronium.

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

Both active 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 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 take **ULTIBRO BREEZHALER** regularly even if you feel fine.

When it should not be used:**Do not use **ULTIBRO BREEZHALER**:**

- **If you have a severe allergy to indacaterol maleate or glycopyrronium bromide or any other component of **ULTIBRO BREEZHALER**. Ask your doctor, nurse or pharmacist if you are not sure.**
- **To treat sudden, severe symptoms of COPD such as**

sudden shortness of breath or wheezing.

- **To treat asthma.**
- **ULTIBRO BREEZHALER should not be used in children. COPD does not occur in children.**
- **If you have a lactose or severe milk protein allergy.**
- **If you are younger than 18 years of age.**

What the medicinal ingredient is:

Indacaterol maleate and glycopyrronium bromide

What the non-medicinal ingredients are:

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

What dosage forms it comes in:

Transparent yellow capsules for oral **inhalation**. Each capsule contains 110 mcg indacaterol and 50 mcg glycopyrronium.

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

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

ULTIBRO BREEZHALER should only be used to treat COPD.

ULTIBRO BREEZHALER should not be used to treat asthma.

You are advised that in patients with asthma, long-acting beta₂-agonist (LABA) medicines, may increase the chance of death from asthma problems. In a large asthma study, more patients who used another LABA medicine (salmeterol) died from asthma problems compared with patients who did not use that LABA medicine. This finding with salmeterol is considered a class effect of LABA, including indacaterol maleate, one of the active ingredients of **ULTIBRO BREEZHALER**.

BEFORE you use **ULTIBRO BREEZHALER talk to your doctor, nurse or pharmacist if you:**

- Are pregnant or planning to become pregnant;
- Are a breast-feeding mother;
- Are an asthmatic (in this case you should not be treated with **ULTIBRO BREEZHALER**);
- Have heart problems, such as rapid or irregular heart beat or abnormal electrical signal called “prolongation of the QT interval”;
- Have high blood pressure;
- Have seizures or fits;
- Have thyroid gland problems or disease;

- Suffer from diabetes;
- Are taking similar medicines for your lung disease;
- Are taking any medications including eye drops, this includes medications you can buy without prescription;
- Have problems with your kidneys;
- Have severe liver problems;
- Have eye problems, such as glaucoma or eye pain, blurred vision, see halos around lights or coloured images;
- Have an enlarged prostate, problems passing urine, or painful urination;
- Have a severe allergy to milk proteins. Ask your doctor if you are not sure;
- Have had allergies to atropine or related medicines, for example ipratropium or tiotropium;
- Have allergies to food or drugs.

These capsules are intended for inhalation only.

DO NOT SWALLOW.

ULTIBRO 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 ULTIBRO BREEZHALER, tell your doctor immediately if you experience any of the following symptoms:

- **stop taking ULTIBRO BREEZHALER and tell your doctor immediately** if you experience a tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation of ULTIBRO BREEZHALER (signs of paradoxical bronchospasm).
- **stop taking ULTIBRO BREEZHALER and tell your doctor immediately** 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 ULTIBRO 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 ULTIBRO 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.

ULTIBRO 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, nurse 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.

The following may interact with ULTIBRO BREEZHALER:

- Medicines used in the treatment of depression or sad mood (e.g. 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) (e.g. ipratropium, tiotropium, glycopyrronium, aclidinium, umeclidinium).
- Ask your doctor or pharmacist if any of your other medicines are LABA or ipratropium or LAMA containing medicines;
- Medicines that decrease the level of potassium in your blood. These include diuretics (also known as “water tablets” and 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 in the treatment of high blood pressure or other heart problems (e.g. propranolol) or in the treatment of glaucoma (e.g. timolol);
- Ketoconazole (used to treat fungal infections);
- Ritonavir (Anti-HIV medicine);
- Erythromycin (used to treat bacterial infections);
- Verapamil (used to treat high blood pressure, severe chest pain, irregular heartbeat).

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. Do not exceed the recommended dose prescribed by your doctor.

You can inhale ULTIBRO BREEZHALER before or after food or drink.

Usual adult dose:

Inhale the contents of one capsule through the mouth each day, every day at the same time. Inhaling ULTIBRO BREEZHALER at the same time each day will help to minimize your symptoms throughout the day and night and will also help you to remember to use it.

You only need to inhale once a day to help you breathe easier because the effects of ULTIBRO BREEZHALER last for 24 hours.

Use ULTIBRO BREEZHALER even when you have no breathing problems or other symptoms of COPD.

How long to use ULTIBRO BREEZHALER

Keep using ULTIBRO BREEZHALER for as long as your doctor tells you.

COPD is a long-term disease and you should use ULTIBRO BREEZHALER every day and not only when you have breathing problems or other symptoms of COPD.

If you have questions about how long to continue your treatment with ULTIBRO BREEZHALER, talk to your doctor or your pharmacist.

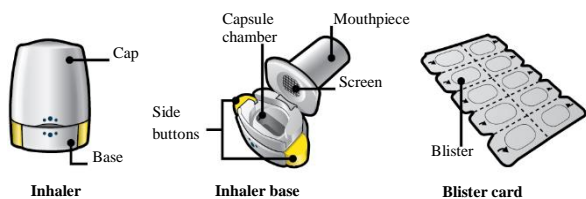
Instructions for use of ULTIBRO BREEZHALER inhaler

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

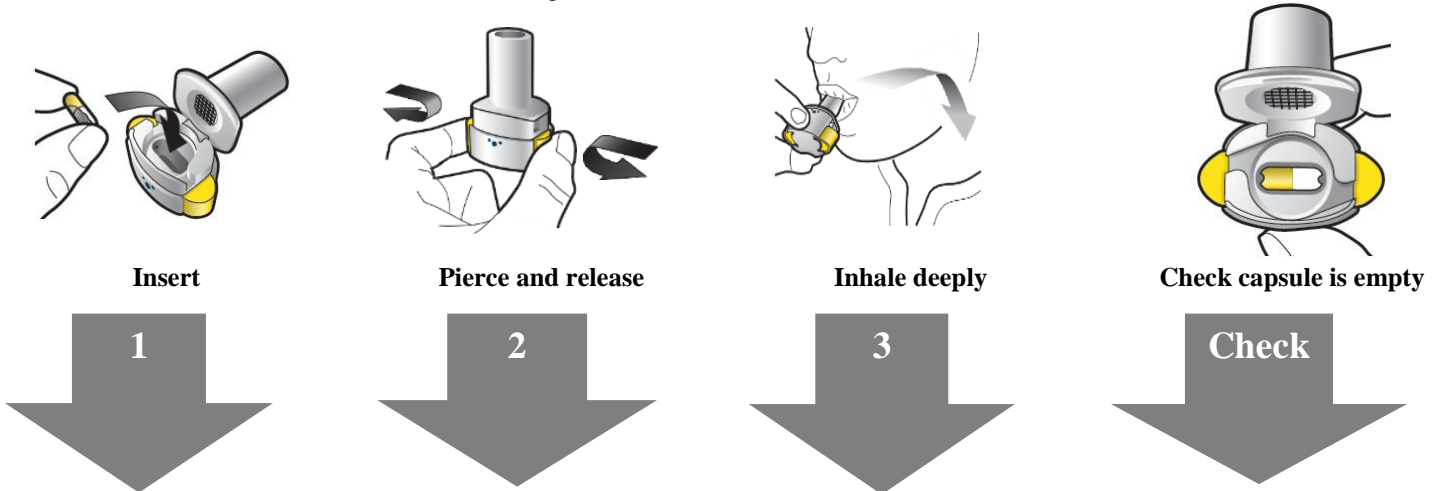
If you have any questions, ask your doctor or pharmacist.

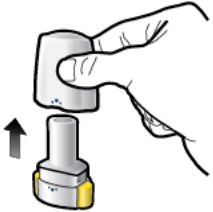


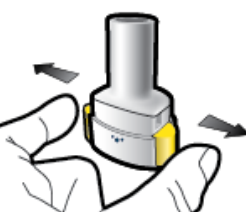


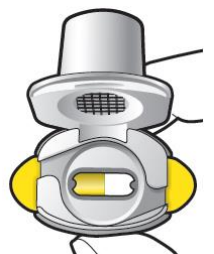
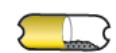

Your ULTIBRO BREEZHALER Inhaler pack contains:

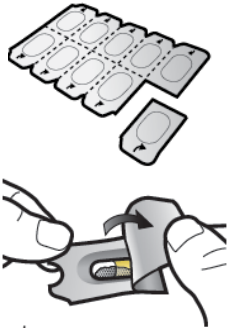
- One ULTIBRO BREEZHALER inhaler
- One or more blister cards, each containing either 6 or 10 ULTIBRO BREEZHALER capsules to be used in the inhaler



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



 <p>Step 1a: Pull off cap</p>  <p>Step 1b: Open inhaler</p>	 <p>Step 2a: Pierce capsule once Hold the inhaler upright. Pierce capsule by firmly pressing both side buttons at the same time. You should hear a noise as the capsule is pierced. Only pierce the capsule once.</p>  <p>Step 2b: Release side buttons</p>	 <p>Step 3a: Breathe out fully Do not blow into the inhaler.</p>  <p>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. <u>Do not press the side buttons.</u></p>	 <p>Check capsule is empty Open the inhaler to see if any powder is left in the capsule.</p> <p>If there is powder left in the capsule: Close the inhaler. Repeat steps 3a to 3c.</p>  <p>Powder remaining</p>  <p>Empty</p>
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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 1d:

Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:

Close inhaler

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.



Remove empty capsule

Put the empty capsule in your household waste.

Close the inhaler and replace the cap.

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.

Frequently Asked Questions**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.

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.

I coughed after inhaling – does this matter?

This may happen. As long as the capsule is empty you have received enough of your medicine.

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.

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.

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.

Overdose:

If you think you have inhaled too much ULTIBRO BREEZHALER, contact your doctor, nurse, pharmacist, 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 doctor or pharmacist right away if this occurs.

Missed Dose:

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

- Blocked nose, sneezing, coughing, headache with or without fever (signs of upper respiratory tract infection)
- Disorders of the voice - hoarse, weak, breathy or strained voice, with or without pain or discomfort in the throat

If any of these affects you severely, **tell your doctor, nurse or pharmacist.**

ULTIBRO BREEZHALER can cause abnormal blood test results such as decreased levels of potassium and increased blood sugar. Your doctor will decide when to perform blood tests and will interpret the results.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor, nurse or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Side effects may include:

- Feeling of pressure or pain in the cheeks and forehead (possible symptoms of sinusitis)
- Runny or stuffy nose, sneezing
- Dizziness
- Headache
- Cough
- Sore throat/or mouth
- Upset stomach, indigestion
- Cavities
- Pain in muscles, bones or joints
- Pain in extremities (e.g. arms or legs)
- Fever
- Chest pain
- Problem falling asleep
- Tingling or numbness
- Nose bleeds
- Dry mouth
- Skin itching/rash
- Muscle spasm
- Tiredness
- Nausea, vomiting, diarrhea and abdominal pain (possible symptoms of gastroenteritis)
- Combination of sore throat, runny nose (signs of nasopharyngitis)
- Fast heart beat
- Irregular heart beat (palpitations)
- Swollen hands, ankles and feet
- Muscle pain, aches or tenderness

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 medical help
		Only if severe	In all cases	
Uncommon	Crushing chest pain with increased sweating (signs of insufficient blood and oxygen supply of the heart). This may be a serious heart problem.			✓
	Irregular heartbeat	✓		
	Paradoxical Bronchospasm: Sudden worsening of shortness of breath and wheezing right after inhaling ULTIBRO BREEZHALER			✓
	Glaucoma: New or worsened pressure in your eyes, eye pain or discomfort, temporary 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 medical help
		Only if severe	In all cases	
Common	Serious Allergic Reaction: difficulties in breathing or swallowing, swelling of tongue, lips and face, skin rash, itching, and hives			✓
	Increased blood sugar: Increased thirst, frequent urination, increased appetite with weight loss, tiredness		✓	
	Urinary retention: Difficulty and pain when passing urine, needing to go often, urination in a weak stream or drips		✓	
	Bladder Infection: painful and frequent urination		✓	
Not known	Decreased levels of potassium in the blood: Irregular heartbeats, muscle weakness and spasms and generally feeling unwell		✓	
	Angioedema: Swelling mainly of the tongue, lips, face and throat		✓	

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

HOW TO STORE IT

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 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.

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.

MORE INFORMATION

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

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

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