

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrONBREZ® BREEZHALER® **Indacaterol maleate inhalation powder hard capsules**

Read this carefully before you start taking PrONBREZ® 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 ONBREZ BREEZHALER.

Serious Warnings and Precautions

ONBREZ BREEZHALER should only be used to treat your Chronic Obstructive Pulmonary Disease (COPD).

In patients with asthma, taking long-acting beta₂-agonist (LABA) medicines may increase the chance of death from asthma related problems. In a large asthma study, more patients who used another LABA medicine called salmeterol died from asthma related problems compared with patients who did not use salmeterol. This finding applies to all LABA medicines. This includes ONBREZ BREEZHALER which contains an ingredient that is a long-acting beta₂-agonist (LABA).

What is ONBREZ BREEZHALER used for?

ONBREZ BREEZHALER is used in adults. It makes breathing easier for people who have trouble breathing due to a lung disease called COPD. This includes chronic bronchitis and emphysema.

How does ONBREZ BREEZHALER work?

ONBREZ BREEZHALER contains a medicine called indacaterol. Indacaterol belongs to a group of medicines called bronchodilators. They relax the muscles of the small airways in the lungs. This helps open up the airways and makes it easier for air to get in and out of the lungs. When taken regularly, it helps the small airways to remain open.

What are the ingredients in ONBREZ BREEZHALER?

Medicinal ingredients: indacaterol maleate.

Non-medicinal ingredients: gelatine (capsule shell) and lactose monohydrate.

ONBREZ BREEZHALER comes in the following dosage forms:

Capsule for oral inhalation: 75 mcg

ONBREZ BREEZHALER contains:

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

Do not use ONBREZ BREEZHALER

- If you have asthma.

- To treat sudden, severe symptoms of COPD.
- If you are allergic to indacaterol maleate or to any of the ingredients in ONBREZ BREEZHALER. The capsules contain gelatin and lactose.
- If you are under 18 years of age.

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

- have or have had heart problems, such as:
 - a rapid or irregular heart beat (arrhythmia)
 - an abnormal electrical signal called “prolongation of the QT interval”
 - heart disease
 - heart attack
- are taking other long-acting beta₂ agonist medicines.
- have high blood pressure.
- have epilepsy.
- have thyroid gland problems.
- have high blood sugar (diabetes).
- are pregnant or planning to become pregnant. It is not known if ONBREZ BREEZHALER may affect your unborn baby.
- are breastfeeding. It is not known if ONBREZ BREEZHALER passes into your milk and if it can affect your baby.
- you are allergic to lactose or to milk proteins.

Other warnings you should know about:

ONBREZ BREEZHALER does not relieve the sudden symptoms of COPD. You should **always have** a short-acting bronchodilator medicine (a “rescue” medicine) with you to treat sudden symptoms of COPD. If you do not have one, contact your doctor to have one prescribed for you. Get emergency medical care if:

- your breathing problems get worse quickly
- you are using your “rescue” medicine, but it does not relieve your breathing problems

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

- **Signs of paradoxical bronchospasm:** you have a tightness in your chest, coughing, wheezing or feeling breathless right after inhaling the contents of the capsule.
- **Signs of an allergic reaction:** you have trouble breathing or swallowing, swelling of your tongue, lips or face, a skin rash, itching and hives. Do NOT take ONBREZ BREEZHALER again until you have checked with your doctor.

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

- the potassium levels in your blood. Low levels of potassium have been seen in people taking beta₂-agonist medicines, which may increase your risk of having heart arrhythmias.
- blood sugar levels. High blood glucose levels have been seen in people taking beta₂-

agonist medicines. This is important if you have diabetes

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 ONBREZ BREEZHALER:

- Any medicines that may be similar to ONBREZ BREEZHALER (long-acting beta₂ agonist medicines). Using these together with ONBREZ BREEZHALER may increase the risk of experiencing possible side effects
- medicines used to treat depression (such as tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs)).
- 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 (e.g. theophylline) or steroids (e.g. prednisolone)
- beta-blockers used to treat hypertension or other heart problems (e.g. propranolol) or to treat glaucoma (such as timolol)
- medicines that can prolong your QT interval (your heart’s electrical signal).

How to take ONBREZ BREEZHALER:

ONBREZ BREEZHALER is for oral inhalation only.

Follow your doctor’s instructions carefully. Do not take more than the recommended dose.

Usual dose: Inhale the contents of 1 capsule once a day. Take ONBREZ BREEZHALER every day, even when you do not have breathing problems or have symptoms of COPD.

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

- Your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they get worse while you are taking ONBREZ BREEZHALER.
- You are using your fast acting “rescue” medicine more often.

These could be signs that your COPD may be getting worse.

Instructions For Use of ONBREZ BREEZHALER

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

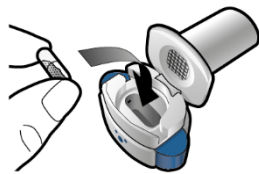
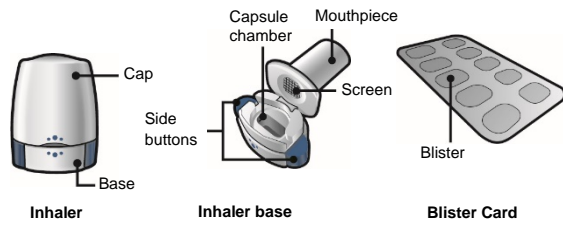
If you have any questions, ask your doctor or pharmacist.

Please read the full Instructions for Use before using ONBREZ BREEZHALER.

Your ONBREZ BREEZHALER Inhaler pack contains:

- 1 BREEZHALER device

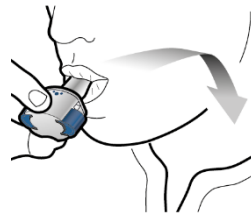
- Blister cards containing the capsules to be used in the inhaler



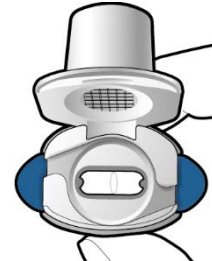
Insert



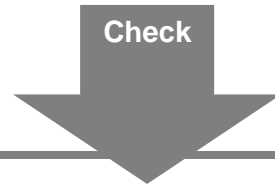
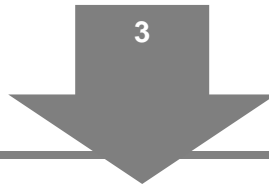
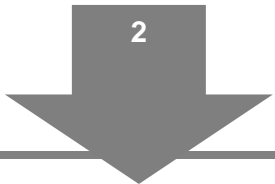
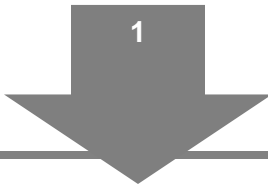
Pierce and release

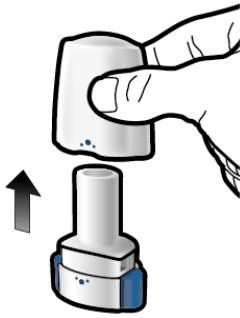
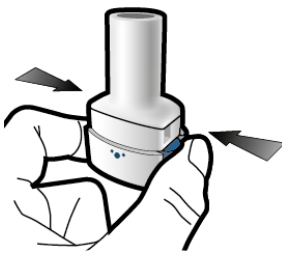

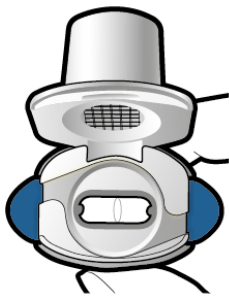


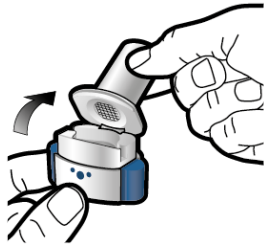
Inhale deeply



Check capsule is empty



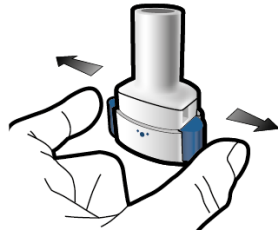
 <p>Step 1a: Pull off cap</p>	 <p>Step 2a: Pierce capsule once</p> <p>Hold the inhaler upright.</p> <p>Pierce capsule by firmly pressing both side buttons at the same time.</p>	 <p>Step 3a: Breathe out fully <u>Do not blow into the inhaler.</u></p>	 <p>Check capsule is empty</p> <p>Open the inhaler to see if any powder is left in the capsule.</p>
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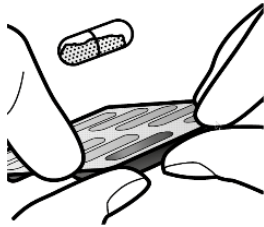
Step 1b:
Open inhaler

You should hear a noise as the capsule is pierced.

Only pierce the capsule once.



Step 2b:
Release side buttons



Step 1c:
Remove the capsule by pushing it through the foil.

Do not swallow the capsule.



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.

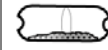


Step 3c:
Hold breath

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

If there is powder left in the capsule:

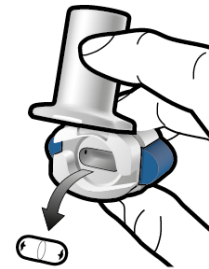
- Close the inhaler.
- Repeat steps 3a to 3c.



Powder Remaining



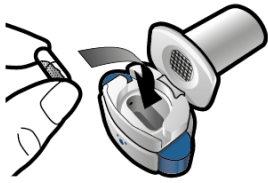
Empty



Remove empty capsule

Put the empty capsule in your household waste.

Close the inhaler and replace the cap.



Step 1d:

Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:

Close inhaler

Important Information

- **Onbrez Breezhaler** capsules must always be stored in the blister card and only removed immediately before use.
- Do not swallow the capsule.
- Do not use the **Onbrez Breezhaler** capsules with any other inhaler.
- Do not use the **Onbrez 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.

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.

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.

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 taken too much ONBREZ BREEZHALER, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take your dose, you should take it as soon as you remember. ONBREZ BREEZHALER should not be used more than one time in 24 hours.

What are possible side effects from using ONBREZ BREEZHALER?

These are not all the possible side effects you may feel when taking ONBREZ BREEZHALER. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects include:

- Nausea
- Upper respiratory tract infections
- Muscle cramp
- Headache
- Cough
- Irritation of the mouth or throat

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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	
UNCOMMON Bronchospasm (a sudden narrowing of the airway): trouble breathing with wheezing or coughing			✓
Muscle weakness, muscle spasms, or an abnormal heart rhythm (low blood potassium level)			✓

Allergic reaction: fainting (low blood pressure), rash, hives or itching, swelling of the tongue, lips and face or difficulty in swallowing			✓
UNKNOWN Fast or irregular heartbeat	✓		

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

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
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Storage:

Store the capsules at room temperature (15 to 25°C) in the original package to protect from light and moisture. Remove capsules from package only when ready to use. Keep out of the reach and sight of children. Do not use after the expiry date shown on the box.

If you want more information about ONBREZ 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 (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website <http://www.novartis.ca>, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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