

CONSUMER INFORMATION

Pr**ONBREZ[®] BREEZHALER[®]**
Indacaterol maleate

This leaflet is part III of a three-part "Product Monograph" published when ONBREZ[®] 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 ONBREZ[®] BREEZHALER[®]. Contact your doctor or pharmacist if you have any questions about the drug.

Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist. This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses. 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.

ABOUT THIS MEDICATION

What the medication is used for:

ONBREZ[®] BREEZHALER[®] is used to make breathing easier for people who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD).

What it does:

ONBREZ[®] BREEZHALER[®] relaxes the muscles in the walls of the small air passages in the lungs. This helps open up the airways for 24 hours, making it easier for air to get in and out and prevent symptoms, such as wheezing and shortness of breath.

When it should not be used:

Do not use ONBREZ[®] BREEZHALER[®]:

- To treat asthma
- To treat sudden, severe symptoms of COPD
- If you have a severe allergy to ONBREZ[®] BREEZHALER[®] or any of its ingredients. Ask your doctor if you are not sure.
- To treat patients under 18 years of age.

What the medicinal ingredient is:

Indacaterol maleate. 75 mcg indacaterol per capsule.

What the nonmedicinal ingredients are:

Lactose monohydrate and gelatine (capsule shell).

What dosage forms it comes in:

In this pack, you will find a device called an "inhalation device" together with capsules in blister strips.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

ONBREZ[®] BREEZHALER[®] should only be used to treat COPD.

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 may also apply to ONBREZ[®] BREEZHALER[®].

BEFORE you use ONBREZ[®] BREEZHALER[®] talk to your doctor or pharmacist if you:

- 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 epilepsy
- have thyroid gland problems
- have 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.
- are taking certain medications (see Drug interactions section)

ONBREZ[®] BREEZHALER[®] contains lactose (milk sugar) and a small amount of milk proteins. It is possible that allergic reactions may happen in patients who have a severe milk protein allergy.

During the treatment with ONBREZ[®] 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 (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 ONBREZ[®] BREEZHALER[®] again before speaking with your doctor.
- If your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen during your treatment

ONBREZ[®] 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

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular the following medicines:

- medicines used in the treatment of depression or sad mood (e.g. tricyclic antidepressants, monoamine oxidase inhibitors).
- medicines similar to ONBREZ[®] BREEZHALER[®] (other LABA) used for your lung disease as it may increase the risk of experiencing possible side effects
- medicines that decrease the level of potassium in your blood. These include diuretics (also known as “water pills” and used to treat hypertension e.g. hydrochlorothiazide), other bronchodilators such as methylxanthines (e.g. theophylline) or steroids (e.g. prednisolone)
- beta-blockers used in the treatment of hypertension or other cardiac problems (e.g. propranolol) or in the treatment of glaucoma (e.g. timolol)

PROPER USE OF THIS MEDICATION

Follow your doctor’s instructions carefully. Do not exceed the recommended dose.

Usual adult dose

Inhale the contents of one capsule through the mouth each day, everyday at the same time, using the ONBREZ[®] BREEZHALER[®] inhalation device (see How To Use ONBREZ[®] BREEZHALER[®] below), even when you have no breathing problems or other symptoms of COPD.

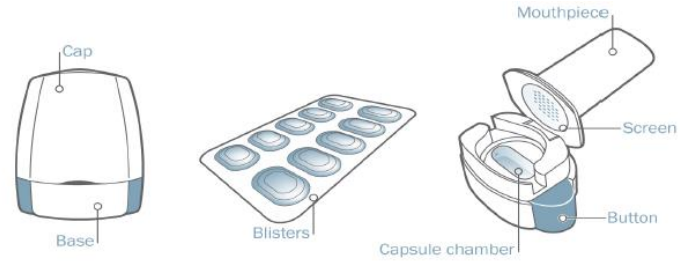
You may inhale this medication in a fasting state or after food or drink.

How to inhale ONBREZ[®] BREEZHALER[®]:

Follow the instructions below. You will breathe in (inhale) the medicine in the ONBREZ[®] BREEZHALER[®] capsules from the ONBREZ[®] BREEZHALER[®] inhalation device. If you have any questions, ask your healthcare provider or pharmacist.

The ONBREZ[®] BREEZHALER[®] package contains ONBREZ[®] BREEZHALER[®] capsules and one ONBREZ[®] BREEZHALER[®] inhalation device.

- The ONBREZ[®] BREEZHALER[®] capsules are supplied in one or more blister cards. Each blister card contains 10 transparent capsules.
- The ONBREZ[®] BREEZHALER[®] inhalation device consists of a cap and a base.



ONBREZ[®]
BREEZHALER[®]
Inhalation device

Blister Card
containing
ONBREZ[®]
BREEZHALER[®]
capsules

Inhaler Base

Your inhalation device is designed to deliver the medicine contained in the capsules. Do not use ONBREZ[®] BREEZHALER[®] capsules with any other capsule inhalation device, and do not use the ONBREZ[®] BREEZHALER[®] inhalation device to take any other capsule medicine.

1. Pull off the cap



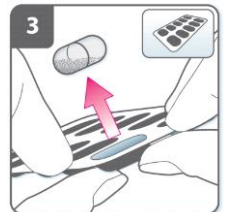
2. Open inhalation device:

Hold the base of the ONBREZ[®] BREEZHALER[®] inhalation device firmly and tilt the mouthpiece to open the inhalation device.



3. Prepare capsule:

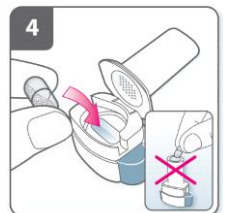
Immediately before use, with dry hands, remove one capsule from the blister.



4. Insert capsule:

Place the capsule into the capsule chamber.

Never place a capsule directly into the mouthpiece.



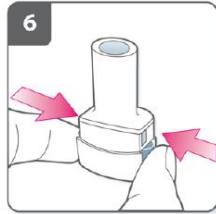
5. Close the inhalation device:

Close the inhalation device fully. You should hear a ‘click’ as it fully closes.

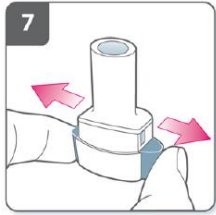


6. Pierce the capsule:

Hold the inhalation device upright with the mouthpiece pointing up. Press both buttons fully one time. You should hear a ‘click’ as the capsule is being pierced. **Do not press the piercing buttons more than once.**

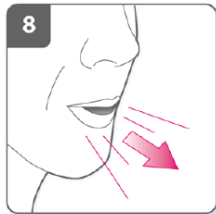


7. Release the buttons fully.



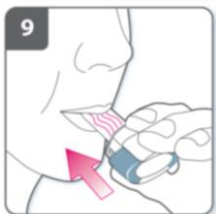
8. Breathe out:

Before placing the mouthpiece in your mouth, breathe out fully. **Never blow into the mouthpiece.**



9. Inhale the medicine:

Before breathing in, place the mouthpiece in your mouth and close your lips firmly around the mouthpiece. Hold the inhalation device with the buttons to the left and right (not up and down). Breathe in rapidly but steadily, as deeply as you can. **Do not press the piercing buttons.**



10. Note:

As you breathe in through the inhalation device, 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 cavity. If this occurs, open the inhalation device and carefully loosen the capsule by tapping the base of the device. **Do not press the piercing buttons to loosen the capsule.** Repeat steps 8 and 9 if necessary.



11. Hold breath:

Continue to hold your breath for at least 5-10 seconds or as long as comfortably possible while removing the inhalation device from your mouth. Then breathe out. Open the inhalation device to see if any powder is left in the capsule. If there is powder left in the capsule, close the inhalation device and repeat steps 8 to 11. Most people are able to empty the capsule with one or two inhalations. Some people occasionally cough soon after inhaling the medicine. If you do, don't worry, as long as the capsule is



empty, you have received the full dose.

12. Remove capsule:

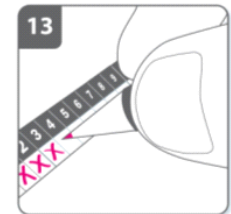
After you have finished taking your daily dose of ONBREZ® BREEZHALER®, open the mouthpiece again, remove the empty capsule by tipping it out, and discard it. Close the inhalation device and replace the cap.



Do not store the capsules in the ONBREZ® BREEZHALER® inhalation device.

13. Mark daily dose tracker:

On the inside of the pack there is a daily dose tracker. Put a mark in today's box if it helps to remind you of when your next dose is due.



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 6).

Remember:

- Do not swallow ONBREZ® BREEZHALER® capsules
- Only use the ONBREZ® BREEZHALER® inhalation device contained in this pack
- ONBREZ® BREEZHALER® capsules must always be stored in the blister, and only removed immediately before use
- Never place an ONBREZ® BREEZHALER® capsule directly into the mouthpiece of the ONBREZ® BREEZHALER® inhalation device
- Do not press the piercing buttons more than once
- Never blow into the mouthpiece of the ONBREZ® BREEZHALER® inhalation device
- Always release the push buttons before inhalation
- Never wash the ONBREZ® BREEZHALER® inhalation device with water. Keep it dry.
- Never take the ONBREZ® BREEZHALER® inhalation device apart
- Always use the new ONBREZ® BREEZHALER® inhalation device that comes with your new ONBREZ® BREEZHALER® medication pack (use a new ONBREZ® BREEZHALER® inhalation device each month)
- Do not store the capsules in the ONBREZ® BREEZHALER® inhalation device
- Always keep the ONBREZ® BREEZHALER® inhalation device and ONBREZ® BREEZHALER® capsules in a dry place

Overdose:

If you have accidentally inhaled too much ONBREZ® BREEZHALER® or if someone else accidentally inhaled your medicine, contact a doctor or hospital for advice immediately.

Show the pack of ONBREZ[®] BREEZHALER[®]. Medical attention may be needed.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget a dose, inhale the next dose on the usual time the next day. Do not take a double dose to make up for a forgotten dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ONBREZ[®] BREEZHALER[®] can cause side effects in some people.

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

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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediately emergency medical attention
		Only if severe	In all cases	
Uncommon	Bronchospasm with wheezing or coughing and difficulty in breathing			✓
	Muscle weakness, muscle spasms, or an abnormal heart rhythm (low blood potassium level)			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediately emergency medical attention
		Only if severe	In all cases	
	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	✓		

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

HOW TO STORE IT

Store ONBREZ[®] BREEZHALER[®] at room temperature between 15 to 25°C. Protect ONBREZ[®] BREEZHALER[®] 75 mcg capsules from light and moisture. Do not use after the expiry date shown on the box.

ONBREZ[®] BREEZHALER[®] capsules must always be stored in the blister, and only removed immediately before use.

Keep ONBREZ[®] BREEZHALER[®] and all medicines out of the 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

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