

ONBREZ® BREEZHALER®

Indacaterol maleate (150 microgram and 300 microgram)

What is in this leaflet

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What Onbrez Breezhaler is used for

Onbrez Breezhaler contains an active substance called indacaterol. This medicine belongs to a group of medicines called bronchodilators. When you inhale it, it helps you breathe more easily. You use it with a device called an inhaler (only use the Onbrez Breezhaler inhaler contained in this pack). In this pack, you will find an inhaler and capsules (in blister strips) that contain the medicine as inhalation powder. The Onbrez Breezhaler inhaler enables you to inhale the medicine contained in a capsule. 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). Regular, once a day, use of Onbrez Breezhaler will help to minimise the effects of the disease on your everyday life.

How Onbrez Breezhaler works

Onbrez Breezhaler relaxes the muscles in the walls of the small air passages in the lungs. This helps open up the airways, making it easier for air to get in and out.

If you have any questions about how Onbrez Breezhaler works or why it has been prescribed for you, ask your doctor.

Before you use Onbrez Breezhaler

Follow all the doctor's instructions carefully. They may differ from the

general information contained in this leaflet.

When you must not use it

- If you have ever had an unusual or allergic reaction to indacaterol or to any other ingredients of this product listed at the end of this leaflet.
- If either of these apply to you, tell your doctor without using Onbrez Breezhaler.
- If you think you may be allergic, ask your doctor for advice

Pregnancy and breast-feeding

If you are pregnant or think that you may be pregnant, or if you are breast-feeding, tell your doctor who will discuss with you whether you can use Onbrez Breezhaler.

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

Before you start to use it

Before using Onbrez Breezhaler, tell your doctor if any of the following applies to you:

- if you are an asthmatic (in this case you should not be treated with Onbrez Breezhaler)
- if you have heart problems
- if you suffer from epilepsy
- if you have thyroid gland problems
- if you suffer from diabetes
- if you are taking similar medicines for your lung disease (see section "Taking other medicines")

Food and drink

You can inhale Onbrez Breezhaler before or after food or drink.

Older people (65 years old and over)

You can use Onbrez Breezhaler if you are aged 65 years and over at the same dose as for other adults.

Children and adolescents (less than 18 years of age)

Onbrez Breezhaler should not be given to children or adolescents.

Taking other medicines

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 (e.g. tricyclic antidepressants, monoamine oxidase inhibitors)
- medicines similar to Onbrez Breezhaler used for your lung disease (use of these 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 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)

How to use Onbrez Breezhaler

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

How much to use

The usual dose is the inhalation of the content of one capsule each day, every day.

When to use it

You only need to inhale once a day because the effects of Onbrez Breezhaler last for 24 hours. Inhaling Onbrez Breezhaler at the same time each day will help to minimise your symptoms throughout the day and night. It will also help you remember to use your medicine. Only use the inhaler contained in this pack (Onbrez Breezhaler inhaler). Do not swallow the capsules. Instructions on how to use the Onbrez Breezhaler inhaler are provided at the end of this leaflet.

How long to use Onbrez Breezhaler

Continue your treatment with Onbrez Breezhaler for as long as your doctor tells you.

COPD is a long-term disease and you

should use Onbrez 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 Onbrez Breezhaler, talk to your doctor or your pharmacist.

If you forget to use Onbrez Breezhaler

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.

If you use too much (overdose)

An overdose of indacaterol is likely to lead to increase in heart rate, tremor, abnormal heart rate, headache, nausea, vomiting, drowsiness, problem with heartbeat, too much acid in the body fluids, low in potassium and high blood sugar.

If you have 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.

While you are using Onbrez Breezhaler

Things you must do

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, urticaria (a red, raised itchy rash), skin rash (signs of hypersensitivity reaction)
- If your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen during your treatment

Things you must not do

- Do not swallow Onbrez Breezhaler capsules
- Never wash the Onbrez Breezhaler inhaler with water.

Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Some side effects could be serious

Uncommon: may affect up to 1 in every 100 people

- Symptoms of a hypersensitivity reaction, such as difficulties in breathing or swallowing, swelling of tongue, lips and face, urticaria, skin rash.
- Symptoms of paradoxical bronchospasm like difficulty breathing with wheezing or coughing.

If you experience any of these, tell your doctor straight away.

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common: may affect more than 1 in 10 people

- Combination of sore throat, runny nose, blocked nose, sneezing, coughing, headache with or without fever.

Common: may affect up to 1 in every 10 people.

- Headache
- Dizziness
- Cough
- Muscle spasm
- Sore throat
- Feeling of pressure or pain in the cheeks and forehead (inflammation of the sinuses)
- Muscle pain
- Swollen hands, ankles and feet
- Crushing chest pain (heart problems)
- Palpitations
- Excessive thirst, high urine output, increased appetite with weight loss, tiredness, high level of sugar in the blood (that are

signs of a disease called diabetes)

- Runny nose
- Pain in bones or joints
- Chest pain
- Itching/Rash

Uncommon: may affect up to 1 in every 100 people.

- Irregular heart beat
- Fast heart beat
- Pain in muscles
- Tingling or numbness

Some people occasionally cough soon after inhaling the medicine. Cough is a common symptom in COPD patients. If you experience coughing briefly after inhaling the medicine, do not worry, as long as the capsule is empty, you have received the full dose.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Onbrez Breezhaler

Storage

- Do not store above 30°C
- Do not use after the expiry date shown on the box
- Store in the original package
- Store in a dry place protected from heat and moisture
- Keep out of the reach and sight of children

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

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

150 microgram capsules are yellowish transparent (uncolored). They have a **black** product code "IDL 150" printed

above and **black** company logo printed under black bar.
300 microgram capsules are yellowish transparent (uncolored). They have a **blue** product code "IDL 300" printed above and **blue** company logo printed under blue bar.

Ingredients

- Active ingredient

- The active substance is indacaterol. Each capsule contains 150 microgram or 300 microgram indacaterol as indacaterol maleate.

- Inactive ingredients

- The other ingredients are lactose and gelatin.

MAL Number

Onbrez Breezhaler 150mcg Inhalation Powder Hard Capsule:
MAL20102095ACRZ

Onbrez Breezhaler 300mcg Inhalation Powder Hard Capsule:
MAL20102096ACRZ

Manufacturer

Siegfried Barbera, S.L.
Ronda de Santa Maria 158, 08210
Barbera del Valles, Barcelona, Spain.

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
Level 18, Imazium,

No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor

Information Issued
27/07/2020

Date of revision

10/01/2022

Serial number

NPRA (R1/4) 12012022/017

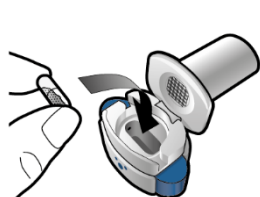
INSTRUCTIONS FOR USE OF ONBREZ BREEZHALER INHALER

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

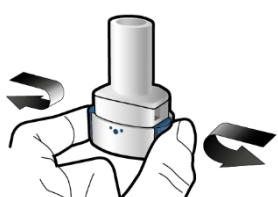
See also section **How to use ONBREZ BREEZHALER** of this leaflet.

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

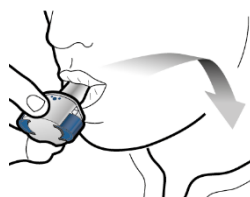
Please read the full Instructions for Use before using the Onbrez Breezhaler.



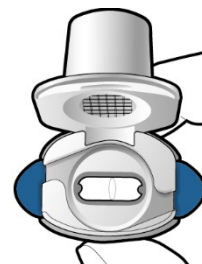
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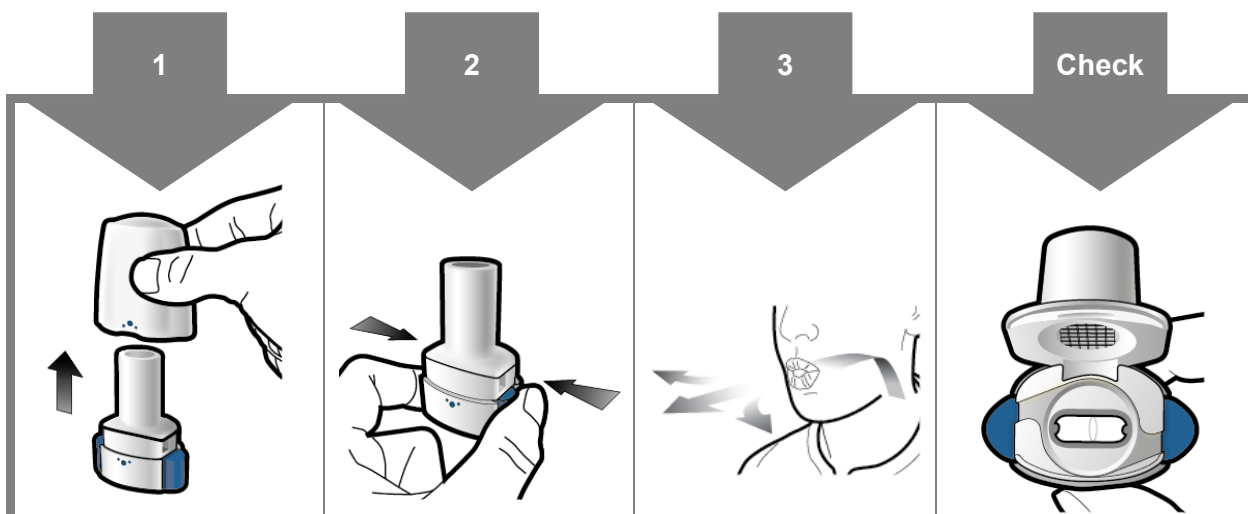
Pierce and release

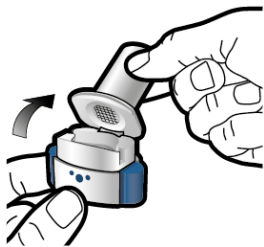
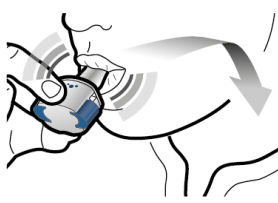
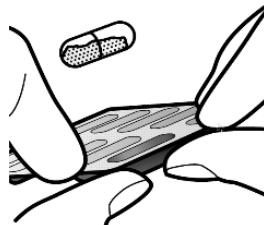
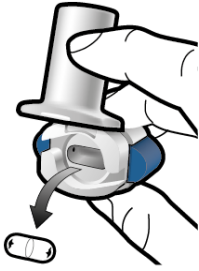


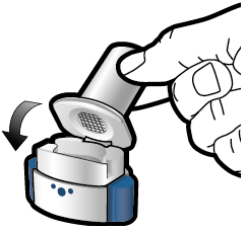
Inhale deeply

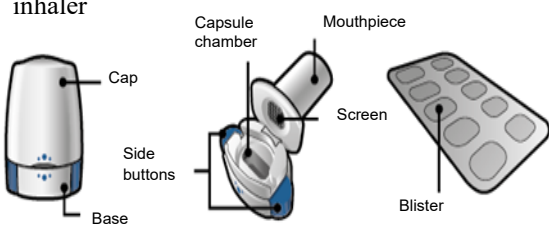


Check capsule is empty



Step 1a: Pull off cap 	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. <u>Only pierce the capsule once.</u>	Step 3a: Breathe out fully <u>Do not blow into the inhaler</u> 	Check capsule is empty Open the inhaler to see if any powder is left in the capsule. If there is powder left in the capsule: • Close the inhaler. • Repeat steps 3a to 3c.
Step 1b: Open inhaler  Step 1c: Remove capsule Remove one capsule from the blister. <u>Do not swallow the capsule.</u>	 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. <u>Do not press the side buttons.</u> 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.	  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 <u>Never place a capsule directly into the mouthpiece.</u>			• 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.
 Step 1e: Close inhaler			

Your Onbrez Breezhaler Inhaler pack contains: • One Onbrez Breezhaler inhaler • One or more blister cards, each containing either 6 or 10 Onbrez Breezhaler capsules to be used in the inhaler  Inhaler Inhaler base Blister Card	Frequently Asked Questions Why didn't the inhaler make a noise when I inhaled?	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.
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	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.	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.
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