

# ONBREZ<sup>®</sup> BREEZHALER<sup>®</sup>

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 taking Onbrez Breezhaler can experience side effects although not everybody gets them.

***Some side effects are very common***

*These side effects may affect more than 1 in every 10 patients*

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

If any of these affects you severely, tell your doctor.

***Some side effects are common***

*These side effects may affect between 1 and 10 in every 100 patients.*

- 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

If any of these affects you severely, tell your doctor.

***Some side effects are uncommon***

*These side effects may affect between 1 and 10 in every 1,000 patients.*

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

If any of these affects you severely, tell your doctor.

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, don't worry, as long as the capsule is empty, you have received the full dose. 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.

***Some side effects could be serious***

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

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers →Reporting).

**Storage and disposal of Onbrez Breezhaler**

- **Storage**

- Do not store above 30<sup>0</sup>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: Black product code "IDL 150" printed above and black company logo printed under black bar on yellowish transparent uncoloured capsule.

300 microgram: Blue product code "IDL 300" printed above and blue company logo printed under blue bar on yellowish transparent uncoloured capsule.

**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: MAL20102095AR

Onbrez Breezhaler 300mcg Inhalation Powder Hard Capsule: MAL20102096AR

**Manufacturer**

Novartis Pharma Stein AG, Schaffhauserstrasse, CH-4332, Stein, Switzerland.

**Product Registration Holder**

Novartis Corporation (Malaysia) Sdn. Bhd. Level 22, Tower B, Plaza 33, No. 1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya

Information Issued 30/09/2013

Date of revision 05/03/2015

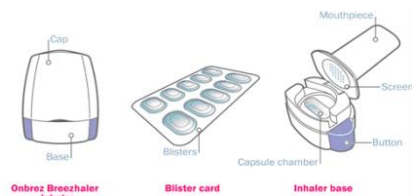
**INSTRUCTIONS FOR USE OF ONBREZ BREEZHALER INHALER**

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.**

**Your ONBREZ BREEZHALER pack:**



Each Onbrez Breezhaler pack contains:

- one Onbrez Breezhaler inhaler
- blisters containing Onbrez Breezhaler capsules to be used in the inhaler

**Do not swallow Onbrez Breezhaler capsules:**

The ONBREZ BREEZHALER inhaler enables you to inhale the medicine contained in an Onbrez Breezhaler capsule.

**Only use the Onbrez Breezhaler inhaler contained in this pack.**

Do not use Onbrez Breezhaler capsules with any other inhaler, and do not use Onbrez Breezhaler inhaler to take any other capsule medicine.

**How to use your inhaler**

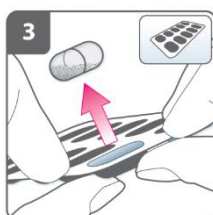


**Pull off cap.**



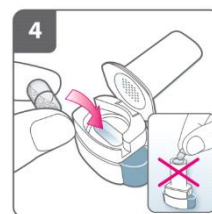
**Open inhaler:**

Hold the base of the inhaler firmly and tilt the mouthpiece to open the inhaler.



**Prepare capsule.**

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



**Insert capsule:**

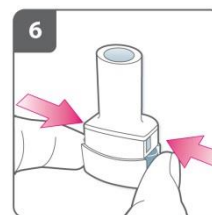
Place the capsule into the capsule chamber.

**Never place a capsule directly into the mouthpiece.**



**Close the inhaler:**

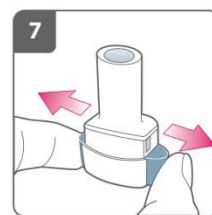
Close the inhaler fully. You should hear a 'click' as it fully closes.



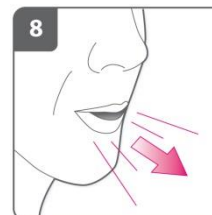
**Pierce the capsule:**

Hold the inhaler 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.**



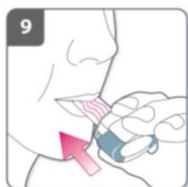
**Release the buttons fully.**



**Breathe out:**

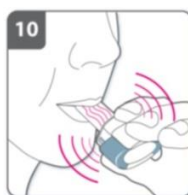
Before placing the mouthpiece in your mouth, breathe out fully.

**Never blow into the mouthpiece.**

**Inhale the medicine:**

Before breathing in, place the mouthpiece in your mouth and close your lips firmly around the mouthpiece. Hold the inhaler 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.**

**Note:**

As you breathe in through the inhaler, the capsule spins around in the chamber and you should hear a whirring noise. You will experience a sweet flavour 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 inhaler 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.

**Hold breath:**

**Continue to hold your breath** for at least 5-10 seconds or as long as comfortably possible while removing the inhaler from your mouth. Then breathe out.

Open the inhaler to see if any powder is left in the capsule. If there is powder left in the capsule, close the inhaler and repeat steps 8 to 11. Most people are able to empty the capsule with one or two inhalations.

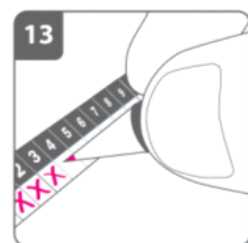
Some people occasionally cough soon after inhaling the medicine. If you do, don't worry, as long as the capsule is

empty, you have received the full dose.

**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 inhaler and replace the cap.

**Do not store the capsules in the ONBREZ BREEZHALER inhaler.**

**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.

**REMEMBER:**

- **Do not swallow ONBREZ BREEZHALER capsules**
- **Only use the ONBREZ BREEZHALER inhaler 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 inhaler
- Do not press the piercing buttons more than once
- Never blow into the mouthpiece of the ONBREZ BREEZHALER inhaler
- Always release the push buttons before inhalation
- Never wash the ONBREZ BREEZHALER inhaler with water. Keep it dry. See below "How to clean your inhaler"
- Never take the ONBREZ BREEZHALER inhaler apart

- Always use the new ONBREZ BREEZHALER inhaler that comes with your new ONBREZ BREEZHALER medication pack
- Do not store the capsules in the ONBREZ BREEZHALER inhaler
- Always keep the ONBREZ BREEZHALER inhaler and ONBREZ BREEZHALER capsules in a dry place

**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).

**How to clean your inhaler**

Clean your inhaler once a week. Wipe the mouthpiece inside and outside with a clean, dry lint-free cloth to remove any powder residue. Never wash your inhaler with water. Keep it dry.

**Serial number**

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