NOVARTIS

ONBREZ BREEZHALER®

(indacaterol maleate)

150 µg (Dry Powder Inhalation Capsules)

Patient Information Leaflet

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SCHEDULING STATUS: S3

PRODUCT NAME

ONBREZ BREEZHALER® 150 µg (Dry Powder Inhalation Capsules)

The active ingredient of **ONBREZ BREEZHALER 150 µg** is indacaterol maleate equivalent to 150 µg indacaterol.

Please read this leaflet carefully before using ONBREZ BREEZHALER®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care providers.
- **ONBREZ BREEZHALER®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if

What is in this leaflet

1. What ONBREZ BREEZHALER® is and what it is used for
2. What you need to know before you use ONBREZ BREEZHALER®
3. How to use ONBREZ BREEZHALER®
4. Possible side effects
5. How to store ONBREZ BREEZHALER®
6. Contents of the pack and other information

1. What ONBREZ BREEZHALER is and what is its used for

The active ingredient of **ONBREZ BREEZHALER 150 µg** is indacaterol maleate equivalent to 150 µg indacaterol.

Contains sugar: Lactose

ONBREZ BREEZHALER belongs to a group of medicine called bronchodilators. **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** 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 used according to your doctor's instructions.

You use these capsules with 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. **ONBREZ BREEZHALER** inhaler enables you to inhale the medicine contained in a capsule.

2. What you need to know before you use ONBREZ BREEZHALER®

Do not use ONBREZ BREEZHALER

- If you are allergic to indacaterol, any of the ingredients of ONBREZ BREEZHALER listed above or gelatin. If you think you may be allergic, (i.e. if you experience a rash, itching, hives, swelling of the lips, tongue and/or eyes, difficulty breathing or swallowing), ask your doctor for advice.
- **ONBREZ BREEZHALER** contains lactose (milk sugar). If you have severe lactose intolerance, tell your doctor before taking **ONBREZ BREEZHALER**.
- **ONBREZ BREEZHALER** should not be used in patients under 18 years of age.

If this applies to you, **tell your doctor without using ONBREZ BREEZHALER**.

Take special care with ONBREZ BREEZHALER

Tell your doctor or pharmacist before using **ONBREZ BREEZHALER:**

- If you have asthma (in this case you should not be treated with **ONBREZ BREEZHALER**).
- If you suffer from any heart disease or heart problems.
- If you have epilepsy.

- If you suffer from an overactive thyroid.
- If you have a heart disorder, such as an abnormal electrical signal called “prolongation of the QT interval”.
- If you are diabetic (high blood sugar).
- If you are taking similar medicines for your lung disease (see “Using other medicines with ONBREZ BREEZHALER”).

During treatment with **ONBREZ BREEZHALER**, tell your doctor immediately:

- if you experience tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (signs of bronchospasm).
- if your COPD symptoms (breathlessness, wheezing, cough) do not improve or worsen during treatment with **ONBREZ BREEZHALER**.
- if you experience difficulties in breathing or swallowing, swelling of tongue, lips and face, urticaria, skin rash (signs of hypersensitivity reaction).

Using ONBREZ BREEZHALER with food and drink

You can inhale **ONBREZ BREEZHALER** before or after food or drink.

Pregnancy, breastfeeding and fertility

The safety of **ONBREZ BREEZHALER** during pregnancy or while breastfeeding your baby, has not been established.

Driving and using machinery

ONBREZ BREEZHALER has no known effect on the ability to drive and use machines.

If you get headaches or neck pain after treatment with **ONBREZ BREEZHALER**, do not drive or use machines until you know if your **ONBREZ BREEZHALER** affects your performance.

Important information about some of the ingredients of ONBREZ BREEZHALER:

ONBREZ BREEZHALER contains lactose. Patients with the rare hereditary conditions of lactose intolerance should not take ONBREZ BREEZHALER.

ONBREZ BREEZHALER contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Using other medicines with ONBREZ BREEZHALER

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **ONBREZ BREEZHALER** with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice if you are taking any of the following medication:

Tell your doctor, pharmacist or other healthcare professional if you are using:

- Monoamine oxidase inhibitors (MAO inhibitors) or tricyclic antidepressants, which are types of medicines used to treat depression and mood disturbances.
- Medicines similar to **ONBREZ BREEZHALER** used for your lung disease (use of these may increase the risk of experiencing side effects).
- Medicine that decrease the level of potassium in your blood such as:
  - Steroids, which are often used to treat asthma and other inflammatory diseases (e.g. prednisolone).
  - Diuretics, which are “water pills” (e.g. hydrochlorothiazide) used to treat oedema (water retention) e.g. heart failure and high blood pressure.
  - Other bronchodilators such as methylxanthines (e.g. theophylline).
- Beta-blockers, which are a type of medicine used to treat high blood pressure, heart failure, angina, anxiety and abnormal heart rhythm (e.g. propranolol). Certain eye drops used to treat glaucoma may contain beta-blockers (e.g. timolol).

- Some medicines used to treat heart rhythm problems such as amiodarone, disopyramide, procainamide, quinidine, verapamil, ketoconazole and sotalol.

3. HOW TO USE ONBREZ BREEZHALER

Do not share medicines prescribed for you with any other person.

Always use **ONBREZ BREEZHALER** exactly as your doctor or pharmacist has instructed.

Do not exceed the recommended dose.

Do not swallow these capsules. ONBREZ BREEZHALER capsules should be used only with the inhaler provided in the **ONBREZ BREEZHALER** pack. This inhaler has been specially developed for use with **ONBREZ BREEZHALER** capsules.

The usual dose is **one inhalation once a day** (1 capsule = 1 inhalation), every day.

You only need to inhale **once a day** because the effects of **ONBREZ BREEZHALER** last for 24 hours.

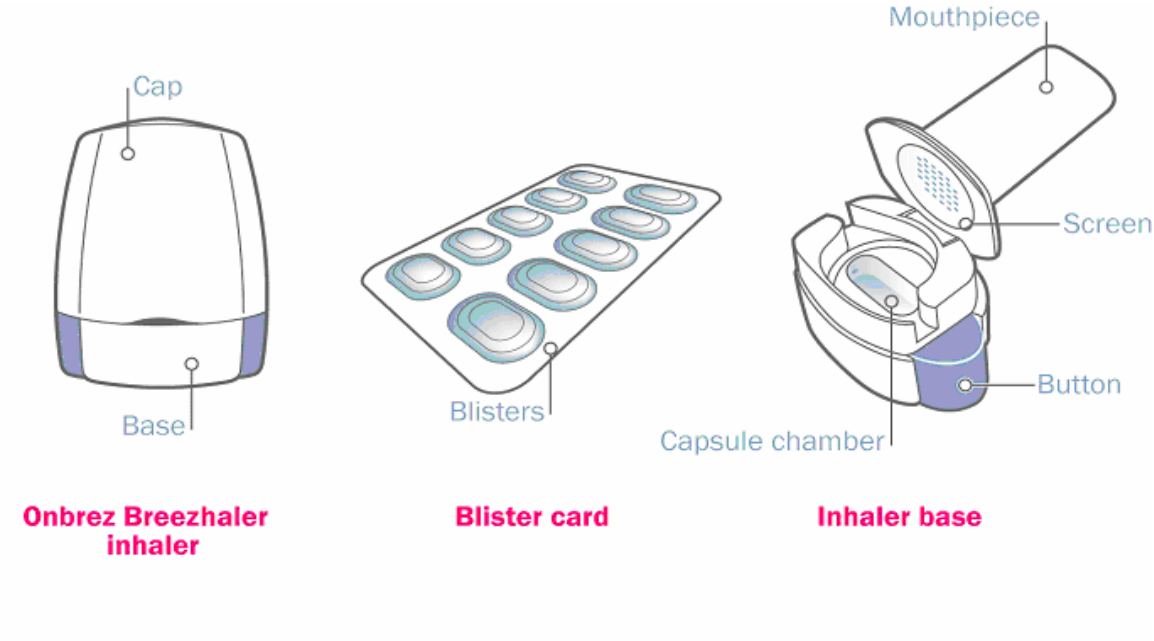
Inhaling ONBREZ BREEZHALER at the same time each day will help to minimise your symptoms throughout the day and night. It will also help you remember to use your medicine.

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.

The capsules should be removed from the blister pack only immediately before use.

Follow the illustrated instructions to learn how to use **ONBREZ BREEZHALER** Inhaler. Make sure your fingers are completely dry so that the capsule does not get wet.

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.

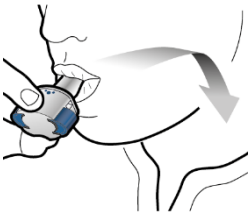
How to use your inhaler



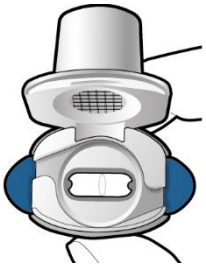
Insert



Pierce and release

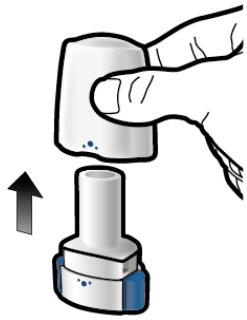


Inhale deeply

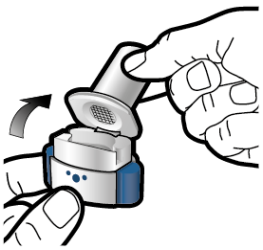


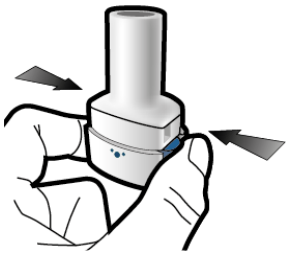
Check capsule is empty

1 **2** **3** **Chec k**



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.

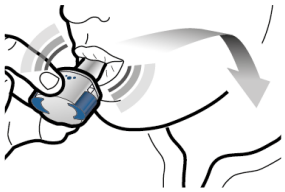
You should hear a noise as the capsule is pierced.

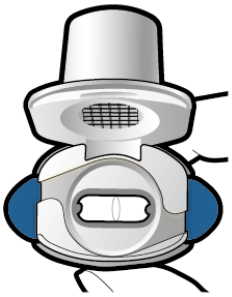
Only pierce the capsule once.



Step 3a:
Breathe out fully

Do not blow into the inhaler.





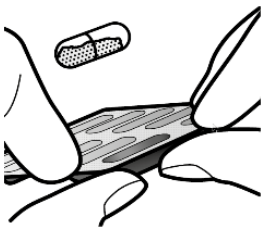
Check capsule is empty

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

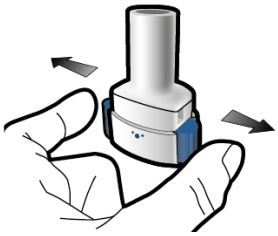
Remove one capsule from the blister.

Do not swallow the capsule.



Step 1d:
Insert capsule

Never place a capsule directly into the mouthpiece.



Step 2b:
Release side buttons

Step 3b:
Inhale medicine deeply

Hold the inhaler as shown in the picture.

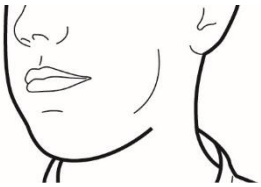
Place the mouthpiece in your mouth and close your lips firmly around it.

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.

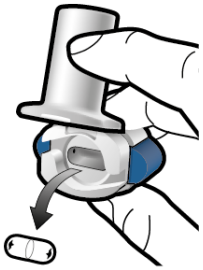


Step 3c:
Hold breath

Hold your breath for up to 5 seconds.



Powder Remaining **Empty**



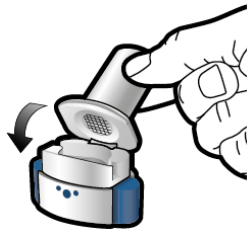
Remove empty capsule

Put the empty capsule in your household waste.

Close the inhaler and replace the cap.

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.

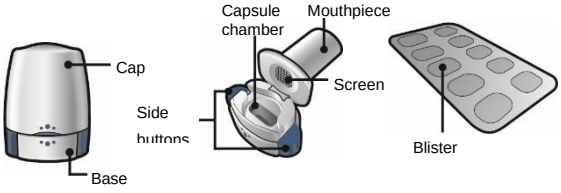


Step 1e:
Close inhaler

- 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.

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?

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?

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.

	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.

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.

If you have the impression that the effect of **ONBREZ BREEZHALER** is too strong or too weak or if you feel that your breathing condition is worsening while taking **ONBREZ BREEZHALER**, **tell your doctor straight away**.

If you have taken more ONBREZ BREEZHALER than you should

If you have accidentally used a lot more **ONBREZ BREEZHALER** than your doctor has prescribed, you may feel sick or have to vomit, or you may experience trembling, headache, fast heartbeat, or sleepiness. Contact your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre **immediately**. Medical treatment may be necessary. Take this leaflet and any remaining capsules with you, so that the doctor knows what you have taken.

If you forget to use ONBREZ BREEZHALER

If you forget a dose, use it as soon as you realise. If it is almost time for your next dose, do not use a double dose of **ONBREZ BREEZHALER** to make up for the one that you missed; just go back to your regular dosing schedule.

4. POSSIBLE SIDE EFFECTS

Not all side effects reported for ONBREZ BREEZHALER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ONBREZ BREEZHALER, please consult your doctor, pharmacist or other healthcare professional.

ONBREZ BREEZHALER can cause side effects.

Some side effects could be serious (less frequent)

- 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

Some side effects are frequent:

• 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.

Other frequent side effects include:

• feeling of pressure or pain in the cheeks and forehead (inflammation of the sinuses)

• cough

• sore throat

• runny nose

• headache

• muscle spasm

• muscle pain

- itching/rash
- dizziness
- palpitations
- crushing chest pain (heart problems)
- swollen hands, ankles and feet
- pain in the bones and joints

• chest pain

• excessive thirst, high urine output, increased appetite with weight loss, tiredness, high levels of sugar in the blood (the signs of high level of sugar in the blood called diabetes).

Some side effects are less frequent:

- 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, but, 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to patientsafety.sacg@novartis.com and via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA`s publications: https://www.sahpra.org.za/Publications/Index/8 By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store ONBREZ BREEZHALER

- Store at or below 30 °C.
- ONBREZ BREEZHALER capsules must always be stored in the blister to protect from moisture and only removed immediately before use.
- Do not store the medicine in the bathroom and or in the sun.

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

- Do not use the capsules after the expiry date printed on the blister or label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

ONBREZ BREEZHALER® 150 µg*:* 30 or 60 capsules in aluminium blister strips and 1 inhaler. Each blister contains 10 capsules.

The other inactive ingredients of **ONBREZ BREEZHALER** are: lactose monohydrate (which contains milk proteins) and gelatin.

IDENTIFICATION OF ONBREZ BREEZHALER

ONBREZ BREEZHALER® 150 µg: Black product code "IDL 150" printed above and black company logo printed under black bar on yellowish transparent (uncoloured) capsule.

Appearance of content*:** White to practically white powder. ***Appearance of capsule shell: *Aspect* - Yellowish transparent (uncoloured) cap and body; **Imprint** - *Cap*: black " " under black bar; *Body:* black "IDL 150" above black bar.

Size: Capsule size 3

ONBREZ BREEZHALER® inhaler: White plastic device protected by a white plastic cap. Colour of push buttons: translucent blue.

HOLDER OF CERTIFICATE OF REGISTRATION:

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

Johannesburg

2090

This leaflet was last revised in:

Date of registration: 07 June 2012

Date of the most recently revised package insert as approved by Council: 23 August 2020

REGISTRATION NUMBERS

ONBREZ BREEZHALER® 150 µg: 44/10.2.1/0544

Namibia: 13/10/2/1/0150	(NS2)
Botswana: BOT1302284	(S2)