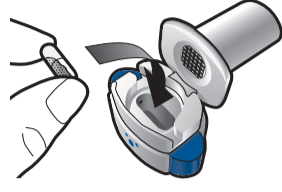
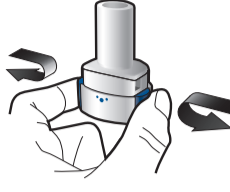
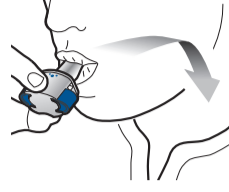

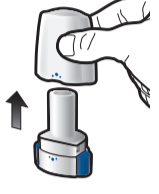
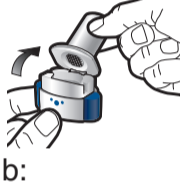
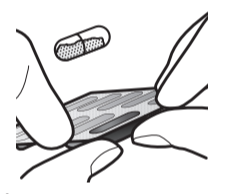
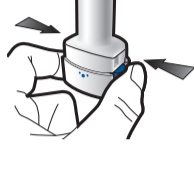







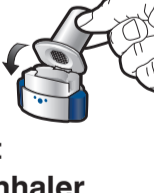


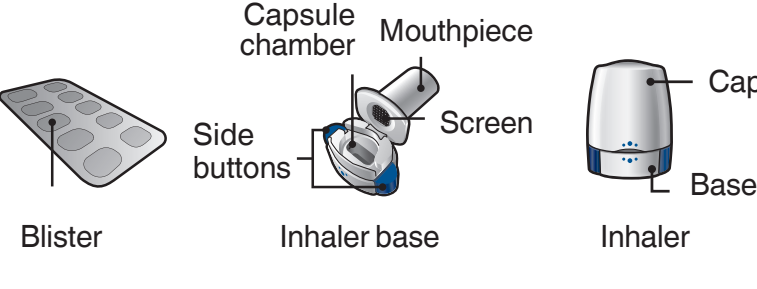


**Instructions for use of Onbrez Breezhaler inhaler**

Please read the full instructions for use before using Onbrez Breezhaler.

 <b>Insert</b> <b>1</b>	 <b>Pierce and release</b> <b>2</b>	 <b>Inhale deeply</b> <b>3</b>	 <b>Check capsule is empty</b> <b>Check</b>
 <b>Step 1a:</b> <b>Pull off cap</b>   <b>Step 1b:</b> <b>Open inhaler</b>   <b>Step 1c:</b> <b>Remove capsule</b> Remove one capsule from the blister. Do not swallow the capsule.	 <b>Step 2a:</b> <b>Pierce capsule once</b> 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>   <b>Step 2b:</b> <b>Release side buttons</b>	 <b>Step 3a:</b> <b>Breathe out fully</b> Do not blow into the inhaler.	 <b>Check capsule is empty</b> Open the inhaler to see if any powder is left in the capsule. If there is powder left in the capsule: <ul style="list-style-type: none"> <li>close the inhaler.</li> <li>repeat steps 3a to 3c.</li> </ul>  <b>Empty</b>  <b>Powder remaining</b>   <b>Remove empty capsule</b> Put the empty capsule in your household waste. Close the inhaler and replace cap.
 <b>Step 1d:</b> <b>Insert capsule</b> Never place a capsule directly into the mouthpiece.	 <b>Step 1e:</b> <b>Close inhaler</b>	 <b>Step 3b:</b> <b>Inhale the medicine deeply</b> 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.	 <b>Step 3c:</b> <b>Hold breath</b> Hold your breath for 5 seconds.
<p>Each Onbrez Breezhaler pack contains:</p> <ul style="list-style-type: none"> <li>One Onbrez Breezhaler inhaler</li> <li>One or more blisters, each containing 10 Onbrez Breezhaler capsules to be used in the inhaler</li> </ul> 		<p><b>Frequently Asked Questions</b></p> <p><b>Why didn't the inhaler make a noise when I inhaled?</b>                      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.</p> <p><b>What should I do if there is powder left inside the capsule?</b>                      You have not received enough medicine. Close the inhaler and repeat steps 3a to 3c.</p> <p><b>I coughed after inhaling – does this matter?</b>                      This may happen. As long as the capsule is empty, you have received enough of the medicine.</p> <p><b>I felt small pieces of the capsule on my tongue – does this matter?</b>                      This can happen. It is not harmful. The chances of the capsule breaking into small pieces increase if the capsule is pierced more than once.</p> <p><b>Cleaning the inhaler</b>                      Wipe the mouthpiece inside and outside with a clean, dry, lint-free cloth to remove any powder residue. Keep the inhaler dry. Never wash the inhaler with water.</p> <p><b>Disposing of the inhaler after use</b>                      Dispose of the inhaler after 30 days of use. Ask the pharmacist how to dispose of medicines and inhalers that are no longer required.</p>	



## **PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

### **Onbrez® Breezhaler® Onbrez® Breezhaler®**

#### **150 mcg**

Inhalation powder  
hard capsules

#### **300 mcg**

Inhalation powder  
hard capsules

Each capsule contains:

Onbrez Breezhaler 150 mcg:

Indacaterol maleate 194 mcg equivalent to 150 mcg indacaterol. The inhaled metered dose is equivalent to 120 mcg indacaterol.

Onbrez Breezhaler 300 mcg:

Indacaterol maleate 389 mcg equivalent to 300 mcg indacaterol. The inhaled metered dose is equivalent to 240 mcg indacaterol.

Inactive ingredients: see section 2 "Important information regarding some of the ingredients of the medicine" and section 6 "Further Information".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, contact the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

#### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Onbrez Breezhaler is used as a maintenance treatment in adults who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD). In COPD, the muscles of the airways tighten, which makes breathing difficult.

Onbrez Breezhaler relaxes these muscles in the lungs, making it easier for air to get in and out of the lungs.

#### **Therapeutic group:**

Selective agonist for beta-2 receptor.

The medicine belongs to a group of medicines for obstructive airways diseases.

#### **2. BEFORE USING THE MEDICINE**

##### **Do not use the medicine if:**

You are sensitive (allergic) to indacaterol (the active ingredient), or to any of the additional ingredients contained in the medicine, listed in section 6.

#### **Special warnings regarding use of the medicine:**

**Before treatment with Onbrez Breezhaler, tell the doctor if:**

- You have asthma (in this case, you should not be treated with Onbrez Breezhaler).
- You have heart problems.
- You suffer from epilepsy.
- You have thyroid gland problems (thyrotoxicosis).
- You suffer from diabetes.

#### **During the treatment with Onbrez Breezhaler:**

- **Stop using the medicine and tell the doctor immediately** if you experience a tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine. These may be signs of a condition called bronchospasm.
- **Tell the doctor immediately** if your COPD symptoms (breathlessness, wheezing, cough) do not improve or if they worsen.

#### **Children and adolescents**

The medicine is not intended for children or adolescents under 18 years of age.

#### **Drug interactions:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially if you are taking:

- Medicines similar to Onbrez Breezhaler to treat breathing problems (i.e., medicines such as salmeterol and formoterol). You are more likely to suffer from side effects.
- Medicines called beta-blockers used for the treatment of high blood pressure or other heart problems (e.g., propranolol) or for the treatment of an eye problem called glaucoma (e.g., timolol).
- Medicines that decrease the level of potassium in the blood. These include:
  - Steroids (e.g., prednisolone)
  - Diuretics, used to treat high blood pressure, e.g., hydrochlorothiazide
  - Medicines to treat breathing problems, e.g., theophylline

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you are pregnant, or are planning to become pregnant, refer to a doctor or pharmacist for advice before treatment with Onbrez Breezhaler.

Do not use Onbrez Breezhaler unless the doctor has told you to do so.

Consult your doctor or pharmacist before taking any medicine.

#### **Driving and operating machinery**

It is unlikely that Onbrez Breezhaler will affect the ability to drive and operate machinery.

#### **Important information regarding some of the ingredients of the medicine**

The medicine contains lactose (milk sugar) (see section 6 "Further Information"). If you have been told by your doctor that you have an intolerance to certain sugars, refer to the doctor before using the medicine.

#### **3. HOW TO USE THE MEDICINE?**

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

#### **The Onbrez Breezhaler dosage**

The dosage and treatment regimen will be determined by the doctor only.

- The usual dosage is generally inhalation of the content of one capsule once a day, every day, using the inhaler. **Do not exceed the recommended dose.**
- Use the inhaler at the same time each day. The effects of Onbrez Breezhaler last for 24 hours. This ensures that there is always enough medicine in your body to help you breathe more easily throughout the day and night. It will also help you to remember to use it.

#### **How to use Onbrez Breezhaler**

- In this pack you will find an inhaler and capsules in a tray (blister) that contains the medicine as inhalation powder. The Onbrez Breezhaler inhaler enables you to inhale the medicine contained in a capsule.
- Only use the capsules with the inhaler provided in this pack (Onbrez Breezhaler inhaler). The capsules should remain in the tray (blister) until you need to use them.
- When you start a new pack, use the new Onbrez Breezhaler inhaler that is supplied in the pack.
- Dispose of each inhaler after 30 days of use.
- Do not swallow capsules.
- Do not open and disperse the contents of the capsule. The powder inside the capsules is intended for inhalation via the inhaler only.
- **Please read the instructions at the end of this leaflet for more information on how to use the inhaler.**

#### **If you accidentally took a higher dosage:**

If you have inhaled too much Onbrez Breezhaler, or if someone else accidentally inhaled the medicine, refer immediately to

a doctor or proceed to the closest hospital emergency room. Present the Onbrez Breezhaler package. Medical attention may be needed. You may notice that your heart is beating faster than usual, or you may have a headache, feel drowsy, feel nauseous or have to vomit.

#### **If you forget to use Onbrez Breezhaler**

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

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

#### **Duration of treatment**

- Continue treatment with Onbrez Breezhaler for as long as your doctor tells you. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor.

- COPD is a long-term disease and Onbrez Breezhaler should be used **every day** and not only when you have breathing problems or other symptoms of COPD.

If you have questions about how long to continue treatment with Onbrez Breezhaler, refer to a doctor or pharmacist.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, use of Onbrez Breezhaler may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Some side effects may be serious. Tell the doctor immediately:

- If you get crushing chest pain (common).
- If you have high blood sugar levels (diabetes). You will feel tired, very thirsty and hungry (without gaining weight) and will pass more urine than usual (common).
- If you get irregular heartbeat (uncommon).
- If you get symptoms of an allergic reaction such as rash, itching, hives, difficulty breathing or swallowing, dizziness (uncommon).
- If you have difficulty breathing with wheezing or coughing (uncommon).

Other side effects may include:

Very common side effects (effects that occur in more than one user in 10):

- Cold-like symptoms. You may experience all or most of the following symptoms: sore throat, runny nose, blocked nose, sneezing, coughing, headache.

Common side effects (effects that occur in 1-10 in 100 users):

- Feeling of pressure or pain in the cheeks and forehead (inflammation of the sinuses)
- Runny nose
- Cough
- Sore throat
- Headache
- Dizziness
- Palpitations
- Muscle spasm
- Swollen hands, ankles and feet (edema)
- Itching/rash
- Chest pain
- Pain in muscles, bones or joints

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

- Fast heartbeat
- Tingling or numbness
- Muscle pain

Some people occasionally cough soon after inhaling the medicine. Cough is a common symptom in COPD patients. If you cough briefly after inhaling the medicine, do not worry. Check your inhaler to see if the capsule is empty, and you received the full dose. If the capsule is empty, you have no reason to worry. If the capsule is not empty, inhale again according to the instructions.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.**

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:  
<https://sideeffects.health.gov.il>

#### **5. HOW TO STORE THE MEDICINE?**

Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from moisture. Do not use the medicine if you notice that the package is damaged or not whole.

#### **6. FURTHER INFORMATION**

**In addition to the active ingredient, the medicine also contains:**

Gelatin, Lactose monohydrate.

Printing ink black (150 mcg only).

Printing ink blue (300 mcg only).

##### Printing ink black

Shellac (E904), Iron oxide black (E172, C.I. 77499), N-butyl alcohol, Water purified, Propylene glycol (E1520), Ethanol, anhydrous, Isopropyl alcohol, Ammonia solution, concentrated

##### Printing ink blue

Shellac (E904), FD&C Blue #1/Brilliant Blue FCF Aluminium Lake (E133, C.I. 42090), N-butyl alcohol, Propylene glycol (E1520), Titanium dioxide (E171, C.I. 77891), Iron oxide black (E172, C.I. 77499), Industrial methylated spirit 74 OP, Isopropyl alcohol, Water purified, Ethanol, anhydrous

Each Onbrez Breezhaler 150 mcg capsule contains 24.806 mg lactose monohydrate.

Each Onbrez Breezhaler 300 mcg capsule contains 24.611 mg lactose monohydrate.

#### **What the medicine looks and the content of the package:**

**Onbrez Breezhaler 150 mcg:** Yellowish transparent (uncoloured) capsules which contain a white powder. "IDL 150" is printed in black above a black line and the Novartis logo (⚖) is imprinted in black under the black line. Content of the pack: 30 capsules + 1 inhaler.

**Onbrez Breezhaler 300 mcg:** Yellowish transparent (uncoloured) capsules which contain a white powder. "IDL 300" is printed in blue above a blue line and the Novartis logo (⚖) is imprinted in blue under the blue line. Content of the pack: 30 capsules + 1 inhaler.

**Registration Holder and Importer and its address:** Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

Onbrez Breezhaler 150 mcg: 144 76 33112

Onbrez Breezhaler 300 mcg: 144 75 33111

Revised in June 2021 according to MOH guidelines.