

Package leaflet: Information for the user

Onbrez[®] Breezhaler 150 microgram inhalation powder, hard capsules Onbrez[®] Breezhaler 300 microgram inhalation powder, hard capsules Indacaterol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 it is used for

What Onbrez Breezhaler is

Onbrez Breezhaler contains the active substance indacaterol which belongs to a group of medicines called bronchodilators. When you inhale it, it relaxes the muscles in the walls of the small air passages in the lungs. This helps open up the airways, making it easier to get air in and out.

What Onbrez Breezhaler is used for

Onbrez Breezhaler is used to make breathing easier for adult patients who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD). In COPD the muscles around the airways tighten. This makes breathing difficult. This medicine relaxes these muscles in the lungs, making it easier for air to get in and out of the lungs.

2. What you need to know before you use Onbrez Breezhaler

Do not use Onbrez Breezhaler

- if you are allergic to indacaterol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Onbrez Breezhaler

- if you have asthma (in this case you should not use Onbrez Breezhaler).
- if you have heart problems.
- if you have epilepsy.
- if you have thyroid gland problems (thyrotoxicosis).
- if you have diabetes.

During treatment with Onbrez Breezhaler,

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

Children and adolescents

Onbrez Breezhaler **should not** be given to **children or adolescents below the age of 18 years**.

Other medicines and Onbrez Breezhaler

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, please tell your doctor if you are using:

- medicines for breathing problems that are similar to Onbrez Breezhaler (i.e. medicines such as salmeterol and formoterol). You may be more likely to get side effects.
- medicines called beta blockers that are used for high blood pressure or other heart problems (such as propranolol), or for the eye problem called glaucoma (such as timolol).
- medicines that lower the amount of potassium in your blood. These include:
 - o steroids (e.g. prednisolone),
 - o diuretics (water tablets) used for high blood pressure such as hydrochlorothiazide,
 - o medicines for breathing problems such as theophylline.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You should not use Onbrez Breezhaler unless your doctor tells you so.

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

Driving and using machines

It is unlikely that Onbrez Breezhaler will affect your ability to drive and use machines.

Onbrez Breezhaler contains lactose

This medicine contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

3. How to use Onbrez Breezhaler

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much Onbrez Breezhaler to use

- The usual dose is to inhale the content of one capsule each day. Your doctor may tell you to use the 150 microgram capsule or the 300 microgram capsule depending on your condition and on how you respond to the treatment. Do not use more than your doctor tells you to use.
- Use your inhaler at the same time each day, the effects 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 blisters) that contain 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 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 the capsules.
- **Please read the instructions at the end of this leaflet for more information about how to use the inhaler.**

If you use more Onbrez Breezhaler than you should

If you have inhaled too much Onbrez Breezhaler or if someone else uses your capsules, tell your doctor immediately or go to the nearest emergency unit. Show the pack of Onbrez Breezhaler. 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 forget to inhale a dose, inhale just one dose at the usual time the next day. Do not inhale a double dose to make up for a forgotten dose.

How long to continue your treatment with Onbrez Breezhaler

- Keep using 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 pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects may be serious. Tell your doctor immediately

- if you get crushing chest pain, (common).
- if you get high levels of sugar in your blood (diabetes). You will feel tired, very thirsty and hungry (without gaining weight) and will pass more urine than usual (common).
- if you get irregular heart beat (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 (may affect more than 1 in 10 people)

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

Common side effects (may affect up to 1 in 10 people)

- 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 (oedema)
- itching/rash
- chest pain
- pain in muscles, bones or joints

Uncommon side effects (may affect up to 1 in 100 people)

- fast heart beat
- tingling or numbness
- muscle pain

Some people occasionally cough soon after inhaling the medicine. Cough is a common symptom in COPD. If you experience coughing briefly after inhaling the medicine, do not worry. Check your inhaler to see if the capsule is empty and that you have received the full dose. If the capsule is empty, there is no need for concern. If the capsule is not empty then inhale again as directed.

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 via (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard
Ireland	HPRA Pharmacovigilance Earlsfort Terrace IRL - Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie
Malta	ADR Reporting The Medicines Authority Post-Licensing Directorate 203 Level 3, Rue D'Argens GŻR-1368 Gżira Website: www.medicinesauthority.gov.mt e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Onbrez Breezhaler

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”. 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 and do not remove until immediately before use.

Do not use this medicine if you notice that the pack is damaged or show signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Onbrez Breezhaler contains

- Each Onbrez Breezhaler 150 microgram capsule contains 150 microgram indacaterol as indacaterol maleate. The other ingredients include lactose and the capsule is made of gelatin.
- Each Onbrez Breezhaler 300 microgram capsule contains 300 microgram indacaterol as indacaterol maleate. The other ingredients include lactose and the capsule is made of gelatin.

What Onbrez Breezhaler looks like and content of the pack

In this pack, you will find an inhaler, together with capsules in blisters. The capsules are transparent (uncoloured) and contain a white powder.

- Onbrez Breezhaler 150 microgram capsules have a **black** product code “**IDL 150**” printed above a **black** bar and a **black** company logo (ℒ) printed below the **black** bar.
- Onbrez Breezhaler 300 microgram capsules have a **blue** product code “**IDL 300**” printed above a **blue** bar and a **blue** company logo (ℒ) printed below the **blue** bar.

The following pack sizes are available:

Carton containing 10 capsules and 1 inhaler.

Carton containing 30 capsules and 1 inhaler.

Multipack comprising 2 packs (each containing 30 capsules and 1 inhaler).

Multipack comprising 3 packs (each containing 30 capsules and 1 inhaler).

Multipack comprising 30 packs (each containing 10 capsules and 1 inhaler).

Not all pack sizes or strengths may be available in your country.

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Manufacturer

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>

INSTRUCTIONS FOR USE OF ONBREZ BREEZHALER INHALER

Please read the following instructions carefully to learn how to use and care for your Onbrez Breezhaler inhaler.

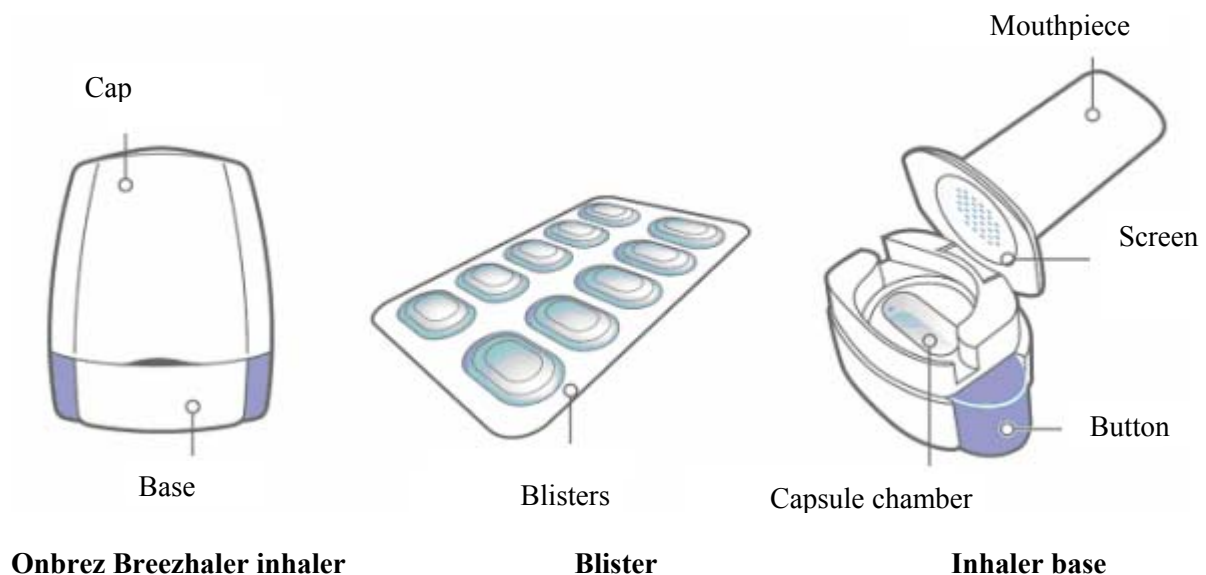
- **Only use the Onbrez Breezhaler inhaler contained in this pack.** Do not use Onbrez Breezhaler capsules with any other inhaler, and do not use Onbrez Breezhaler inhaler to take any other capsule medicine.
- When you start a new pack, only use the new Onbrez Breezhaler inhaler that is supplied in the pack.
- Dispose of each inhaler after 30 days of use.
- Ask your pharmacist how to dispose of medicines and inhalers no longer required.
- **Do not swallow the capsules.** The powder in the capsules is for you to inhale.

Your Onbrez Breezhaler pack:

Each Onbrez Breezhaler pack contains:

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

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



How to use your inhaler



Pull off the cap.



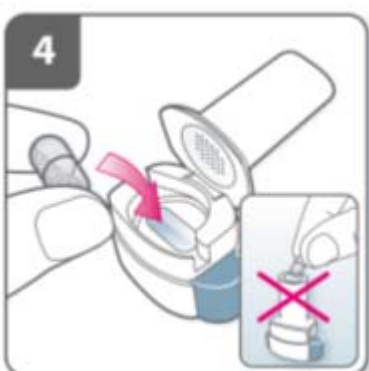
Open inhaler:

Hold the base of the inhaler firmly and tilt the mouthpiece. This opens 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.



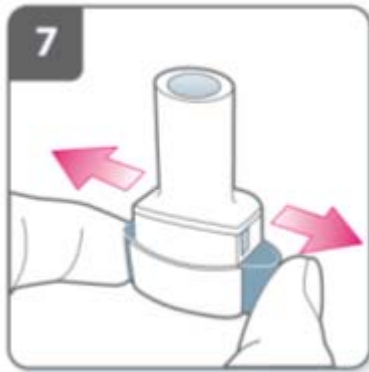
Close the inhaler:

Close the inhaler until you hear a “click”.

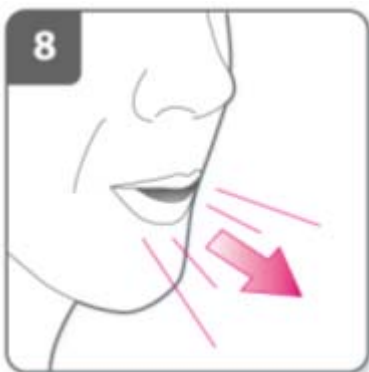


Pierce the capsule:

- Hold the inhaler upright with the mouthpiece pointing up.
- Pierce the capsule by firmly pressing together both side buttons at the same time. **Do this only once.**
- You should hear a “click” as the capsule is being pierced.



Release the side buttons fully.



Breathe out:

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

Do not blow into the mouthpiece.



Inhale the medicine:

To breathe the medicine deeply into your airways:

- Hold the inhaler as shown in the picture. The side buttons should be facing left and right. Do not press the side buttons.
- Place the mouthpiece in your mouth and close your lips firmly around the mouthpiece.
- Breathe in rapidly but steadily and as deeply as you can.



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.

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 accidentally pierced more than once (step 6).

If you do not hear a whirring noise:

The capsule may be stuck in the capsule chamber. If this happens:

- Open the inhaler and carefully loosen the capsule by tapping the base of the inhaler. Do not press the side buttons.
- Inhale the medicine again by repeating steps 8 and 9.



Hold breath:

After you have inhaled the medicine:

- Hold your breath for at least 5-10 seconds or as long as you comfortably can while taking the inhaler out of 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.
- Repeat steps 8, 9, 10 and 11.

Most people are able to empty the capsule with one or two inhalations.

Additional information

Some people may occasionally cough briefly soon after inhaling the medicine. If you do, don't worry. As long as the capsule is empty, you have received enough of your medicine.



After you have finished taking your medicine:

- Open the mouthpiece again, remove the empty capsule by tipping it out of the capsule chamber. Put the empty capsule in your household waste.
- 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 a Onbrez Breezhaler capsule directly into the mouthpiece of the Onbrez Breezhaler inhaler.
- Do not press the side 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 “How to clean your inhaler”.
- Never take the Onbrez Breezhaler inhaler apart.
- Always use the new Onbrez Breezhaler inhaler that comes with your new pack. Dispose of each inhaler after 30 days of use.
- Do not store the capsules in the Onbrez Breezhaler inhaler.
- Always keep the Onbrez Breezhaler inhaler and capsules in a dry place.

How to clean your inhaler

Clean your inhaler once a week.

- Wipe the mouthpiece inside and outside to remove any powder with a clean, dry lint-free cloth.
- Do not wash your inhaler with water. Keep it dry.
- Do not take the inhaler apart.