

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:
 - steroids (e.g. prednisolone),
 - diuretics (water tablets) used for high blood pressure such as hydrochlorothiazide,
 - 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 all capsules have been used.

- 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 (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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 () 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 () 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.

Marketing Authorisation Holder

Novartis Europharm Limited
Vista Building
Elm Park, Merrion Road
Dublin 4
Ireland

Manufacturer

Novartis Farmacéutica SA
Ronda de Santa Maria 158
08210 Barberà del Vallès, Barcelona
Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

Novartis Pharmaceuticals UK Ltd.
Tel: +44 1276 698370

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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 full **Instructions for Use** before using the Onbrez Breezhaler.



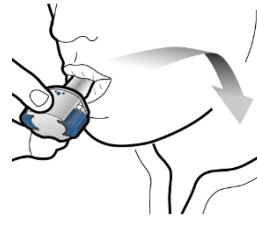
Insert

1



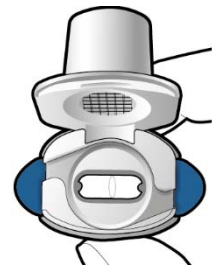
Pierce and release

2



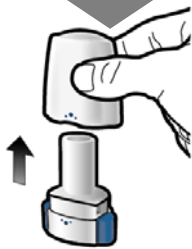
Inhale deeply

3



Check capsule is empty

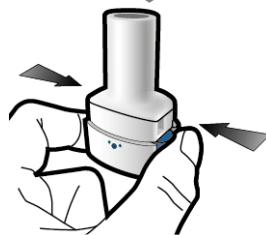
Check



Step 1a:
Pull off cap



Step 1b:
Open inhaler



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.



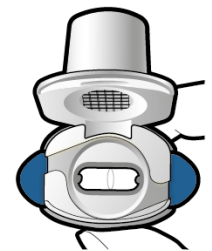
Step 2b:
Release side buttons



Step 3a:
Breathe out fully
Do not blow into the inhaler.



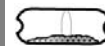
Step 3b:
Inhale medicine deeply
Hold the inhaler as shown in the picture. Place the mouthpiece in your mouth and close your lips firmly around it. Do not press the side buttons.



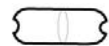
Check capsule is empty
Open the inhaler to see if any powder is left in the capsule.

If there is powder left in the capsule:

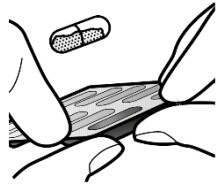
- Close the inhaler.
- Repeat steps 3a to 3c.



Powder remaining



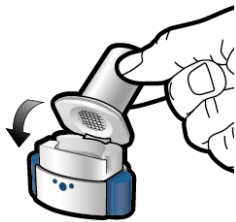
Empty



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.

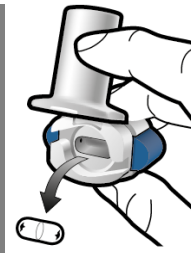


Step 1e:
Close inhaler

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.



Remove empty capsule
Put the empty capsule in your household waste.

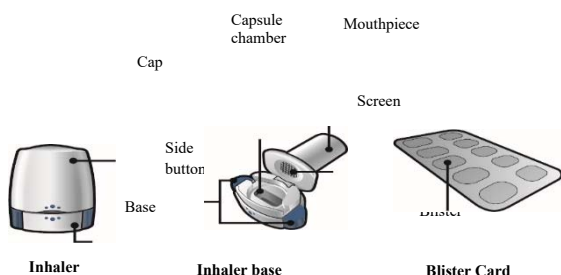
Close the inhaler and replace the cap.

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.
- 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



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?

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.

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.

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.