

Package leaflet: Information for the user

Ultibro[®] Breezhaler[®] 85 micrograms/43 micrograms inhalation powder, hard capsules indacaterol/glycopyrronium

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 any further questions, ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ultibro Breezhaler is and what it is used for
 2. What you need to know before you use Ultibro Breezhaler
 3. How to use Ultibro Breezhaler
 4. Possible side effects
 5. How to store Ultibro Breezhaler
 6. Contents of the pack and other information
- Instructions for use of Ultibro Breezhaler inhaler

1. What Ultibro Breezhaler is and what it is used for

What Ultibro Breezhaler is

This medicine contains two active substances called indacaterol and glycopyrronium. These belong to a group of medicines called bronchodilators.

What Ultibro Breezhaler is used for

This medicine 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 blocks the tightening of these muscles in the lungs, making it easier for air to get in and out of the lungs.

If you use this medicine once a day, it will help to reduce the effects of COPD on your everyday life.

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

Do not use Ultibro Breezhaler

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ultibro Breezhaler if any of the following applies to you:

- you have asthma - this medicine should not be used as a treatment for asthma.
- you have heart problems.
- you have seizure or fits.
- you have thyroid gland problems (thyrotoxicosis).
- you have diabetes.
- you are using any medicines for your lung disease which contain active substances similar (same class) to those in Ultibro Breezhaler (see section "Other medicines and Ultibro Breezhaler").

- you have kidney problems.
- you have severe liver problems.
- you have an eye problem called narrow-angle glaucoma.
- you have difficulty passing urine.

If any of the above applies to you (or you are not sure), **talk to your doctor, pharmacist or nurse before using this medicine.**

During treatment with Ultibro Breezhaler

- **Stop using this medicine and seek medical help immediately** if you experience any of the following:
 - eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes – these may be signs of an acute attack of narrow-angle glaucoma.
 - difficulty breathing or swallowing, swelling of the tongue, lips or face, skin rash, itching and hives (signs of an allergic reaction).
 - tightness of the chest, coughing, wheezing or breathlessness immediately after using this medicine – these may be signs of a condition called paradoxical bronchospasm.
- **Tell your doctor immediately** if your COPD symptoms such as breathlessness, wheezing or cough do not improve or get worse.

Ultibro Breezhaler is used as an ongoing treatment for your COPD. Do not use this medicine to treat a sudden attack of breathlessness or wheezing.

Children and adolescents

Do not give this medicine to children or adolescents below the age of 18 years. This is because it has not been studied in this age group.

Other medicines and Ultibro Breezhaler

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. In particular, please tell your doctor or pharmacist if you are using:

- any medicines that may be similar to Ultibro Breezhaler (contain similar active substances).
- medicines called beta blockers that may be used for high blood pressure or other heart problems (such as propranolol), or for an eye problem called glaucoma (such as timolol).
- medicines that lower the amount of potassium in your blood. These include:
 - steroids (such as prednisolone),
 - diuretics (water tablets) used for high blood pressure (such as hydrochlorothiazide),
 - medicines for breathing problems (such as theophylline).

Pregnancy and breast-feeding

There are no data on the use of this medicine in pregnant women and it is not known whether the active substances of this medicine pass into human milk. Indacaterol, one of the active substances in Ultibro Breezhaler, may prevent labour due to its effect on the uterus.

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 Ultibro Breezhaler unless your doctor tells you to do so.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive and use machines. However, this medicine may cause dizziness (see section 4). If you feel dizzy while taking this medicine, do not drive or use machines.

Ultibro Breezhaler contains lactose

This medicine contains lactose (23.5 mg per capsule). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

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

3. How to use Ultibro Breezhaler

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

How much Ultibro Breezhaler to use

The usual dose is to inhale the content of one capsule each day.

You only need to inhale once a day because the effect of this medicine lasts for 24 hours. Do not use more than your doctor tells you to use.

Elderly (age 75 years and over)

You can use this medicine if you are aged 75 years and over at the same dose as for other adults.

When to inhale Ultibro Breezhaler

Use this medicine at the same time each day. This will also help you to remember to use it.

You can inhale Ultibro Breezhaler any time before or after food or drink.

How to inhale Ultibro Breezhaler

- Ultibro Breezhaler is for inhalation use.
- In this pack, you will find an inhaler and capsules (in blisters) that contain the medicine as inhalation powder. Only use the capsules with the inhaler provided in this pack (Ultibro Breezhaler inhaler). The capsules should remain in the blister until you need to use them.
- Peel the backing away from the blister to open it - do not push the capsule through the foil.
- When you start a new pack, use the new Ultibro Breezhaler inhaler that is supplied in the pack.
- Dispose of the inhaler in each pack after all capsules in that pack have been used.
- Do not swallow the capsules.
- Please read the instructions at the end of this leaflet for more information on how to use the inhaler.

If you use more Ultibro Breezhaler than you should

If you have inhaled too much of this medicine or if someone else accidentally uses your capsules, you must immediately either tell your doctor or go to the nearest emergency unit. Show the pack of Ultibro 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, or you may notice visual disturbances, feel constipated or have difficulty when passing urine.

If you forget to use Ultibro Breezhaler

If you forget to inhale a dose at the usual time, inhale one as soon as possible that day. Then, inhale the next dose as usual the next day. Do not inhale more than one dose on the same day.

How long to continue your treatment with Ultibro Breezhaler

- Keep using Ultibro Breezhaler for as long as your doctor tells you.
- COPD is a long-term disease and you should use Ultibro 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 this medicine, talk to your doctor or pharmacist.

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

4. Possible side effects

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

Some side effects may be serious:

Common (may affect up to 1 in 10 people)

- difficulty breathing or swallowing, swelling of tongue, lips or face, urticaria, skin rash – these may be signs of an allergic reaction.
- feeling tired or very thirsty, having an increased appetite without gaining weight and passing more urine than usual – these may be signs of high level of sugar in the blood (hyperglycaemia).

Uncommon (may affect up to 1 in 100 people)

- crushing chest pain with increased sweating – this may be a serious heart problem (ischaemic heart disease).
- swelling mainly of the tongue, lips, face or throat (possible signs of angioedema).
- difficulty breathing with wheezing or coughing.
- eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes – these may be signs of glaucoma.
- irregular heartbeat.

If you get any of these serious side effects, **seek medical help immediately.**

Other side effects may include:

Very common (may affect more than 1 in 10 people)

- blocked nose, sneezing, cough, headache with or without fever - these may be signs of an upper respiratory tract infection.

Common

- combination of sore throat and runny nose - these may be signs of nasopharyngitis.
- painful and frequent urination – these may be signs of a urinary tract infection called cystitis.
- feeling of pressure or pain in the cheeks and forehead – these may be signs of inflammation of the sinuses called sinusitis.
- runny or stuffy nose.
- dizziness.
- headache.
- cough.
- sore throat.
- upset stomach, indigestion.
- dental caries.
- difficulty and pain when passing urine – these may be signs of a bladder obstruction or urinary retention.
- fever.
- chest pain.

Uncommon

- difficulty sleeping.
- fast heart beat.
- palpitations – signs of abnormal heart beat.
- voice alteration (hoarseness).
- nose bleeds.
- diarrhoea or stomach ache.
- dry mouth.
- itching or rash.
- pain that affects the muscles, ligaments, tendons, joints and bones.
- muscle spasm.
- muscle pain, aches or tenderness.
- pain in arms or legs.

- swollen hands, ankles and feet.
- tiredness.

Rare (may affect up to 1 in 1000 people)

- tingling or numbness.

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 Ultibro 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 25°C.

Store the capsules in the original blister in order to protect from moisture and do not remove until immediately before use.

The inhaler in each pack should be disposed of after all capsules in that pack have been used.

Do not use this medicine if you notice that the pack is damaged or shows 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 Ultibro Breezhaler contains

- The active substances are indacaterol (as maleate) and glycopyrronium bromide. Each capsule contains 143 micrograms of indacaterol maleate equivalent to 110 micrograms of indacaterol and 63 micrograms of glycopyrronium bromide equivalent to 50 micrograms of glycopyrronium. The delivered dose (the dose that leaves the mouthpiece of the inhaler) is equivalent to 85 micrograms of indacaterol (equivalent to 110 micrograms of indacaterol maleate) and 43 micrograms of glycopyrronium (equivalent to 54 micrograms of glycopyrronium bromide).
- The other ingredients of the inhalation powder are lactose monohydrate and magnesium stearate (see section 2 under “Ultibro Breezhaler contains lactose”).

What Ultibro Breezhaler looks like and contents of the pack

Ultibro Breezhaler 85 micrograms/43 micrograms inhalation powder, hard capsules are transparent and yellow and contain a white to almost white powder. They have the product code “IGP110.50” printed in blue under two blue bars on the body and the company logo (U) printed in black on the cap.

In this pack, you will find a device called an inhaler together with capsules in blister strips. Each

blister contains either 6 or 10 hard capsules.

The following pack sizes are available:

Single pack containing 6x1, 10x1, 12x1, 30x1 or 90x1 hard capsules, together with 1 inhaler.

Multipacks containing 96 (4 packs of 24x1) hard capsules and 4 inhalers.

Multipacks containing 150 (15 packs of 10x1) hard capsules and 15 inhalers.

Multipacks containing 150 (25 packs of 6x1) hard capsules and 25 inhalers.

Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Novartis Europharm Limited

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Ireland

Manufacturer

Novartis Farmacéutica SA

Ronda de Santa Maria 158

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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 web site:

<http://www.ema.europa.eu>.

Please read the full **Instructions for Use** before using the Ultibro Breezhaler.



Insert

1



Pierce and release

2



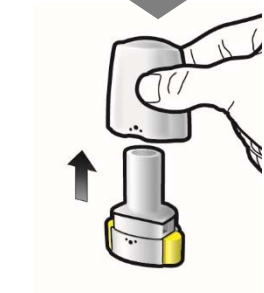
Inhale deeply

3

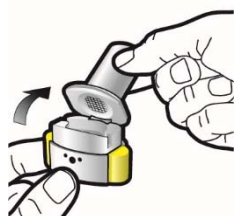


Check capsule is empty

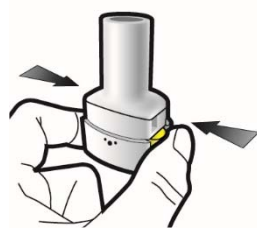
Check



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

Separate one of the blisters from the blister card.

Peel open the blister and remove the capsule.

Do not push the capsule through the foil.

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.



Remove empty capsule

Put the empty capsule in your household waste. Close the inhaler and replace the cap.



Step 3c:

Hold breath

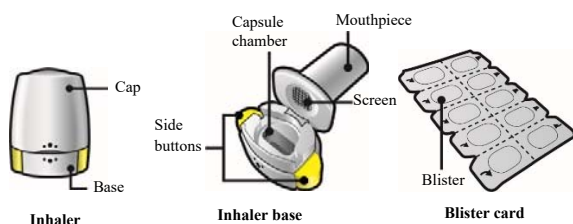
Hold your breath for up to 5 seconds.

Important Information

- Ultibro Breezhaler capsules must always be stored in the blister card and only removed immediately before use.
- Do not push the capsule through the foil to remove it from the blister.
- Do not swallow the capsule.
- Do not use the Ultibro Breezhaler capsules with any other inhaler.
- Do not use the Ultibro 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 Ultibro Breezhaler Inhaler pack contains:

- One Ultibro Breezhaler inhaler
- One or more blister cards, each containing either 6 or 10 Ultibro 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.