

ULTIBRO[®] BREEZHALER[®] Inhalation Powder Hard Capsules

Indacaterol Maleate and Glycopyrronium Bromide (110/50 microgram)

What is in this leaflet

1. What Ultibro Breezhaler is used for
2. How Ultibro Breezhaler works
3. Before you use Ultibro Breezhaler
4. How to use Ultibro Breezhaler
5. While you are using it
6. Side effects
7. Storage and Disposal of Ultibro Breezhaler
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial number
12. Instructions for use of Ultibro Breezhaler Inhaler

What Ultibro Breezhaler is used for

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

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.

How Ultibro Breezhaler works

In COPD the muscles around the airways tighten, making breathing difficult. Ultibro breezhaler blocks tightening of these muscles in the lungs and also 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 you have any questions about how Ultibro Breezhaler works or why this medicine has been prescribed for you, ask your doctor.

Before you use Ultibro Breezhaler

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

When you must not use it

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 Product Description).

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.

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.

Before you start to use it

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 seizures or fits
- you have thyroid gland problems (thyrotoxicosis)
- you have diabetes
- you are using any medicines for your lung disease which contain active substance similar (same class) to those in Ultibro Breezhaler (see section "Taking other medicines")
- 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.

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 taking this medicine.

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

Taking other medicines

Tell your doctor or a 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)

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.

- Ultibro Breezhaler is for inhalation use
- In this pack, you will find an inhaler and capsules (in blister strips) that contain the medicine as inhalation powder. Only use the capsule 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.

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 use 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 long to use 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 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.

If you use too much (overdose)

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 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.

While you are using it

Things you must do

During the 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.

Things you must not do

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.

Things to be careful of

Driving and using machines

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

Side effects

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

Some side effects could 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 (ischemic 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 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 1,000 people)

- Tingling or numbness

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Ultibro Breezhaler

- Storage

- Keep this medicine out of the reach and sight of children
- Do not use after the expiry date which is stated on the carton box 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

show signs of tampering.

- Disposal

- 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 to protect the environment.

Product Description

What it looks like

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

Transparent yellow cap and natural transparent body capsules containing a white to practically white powder, with the product code "IGP110.50" printed in blue under two blue bars on body and

the company logo (L) printed in black on cap.

Each capsule contains 110 microgram of indacaterol and 50 microgram of glycopyrronium bromide active substance.

Ingredients:

- Active ingredients

The active substances are indacaterol maleate and glycopyrronium bromide. Each capsule contains 143 micrograms indacaterol maleate equivalent to 110 micrograms indacaterol and 63 micrograms glycopyrronium bromide equivalent to 50 micrograms 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)

- Inactive ingredients

The other ingredients are:

- Capsule fill: Lactose monohydrate, magnesium stearate (See section Before you use Ultibro Breezhaler).
- Capsule shell components: Hypromellose, purified water, carrageenan, potassium chloride, FD&C Yellow5/Tartrazine.

Pack size:

Each Ultibro Breezhaler pack contains 30 capsules and 1 inhaler.

MAL Number:

MAL15025045ACRZ

Manufacturer

Siegfried Barbera, S.L.,
Ronda de Santa Maria, 158 08210
Barbera del Valles, Barcelona, Spain.

Product Registration Holder

Novartis Corporation (Malaysia) Sdn Bhd

Level 18, Imazium,
No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor

Information Issued

23/06/2020

Date of revision

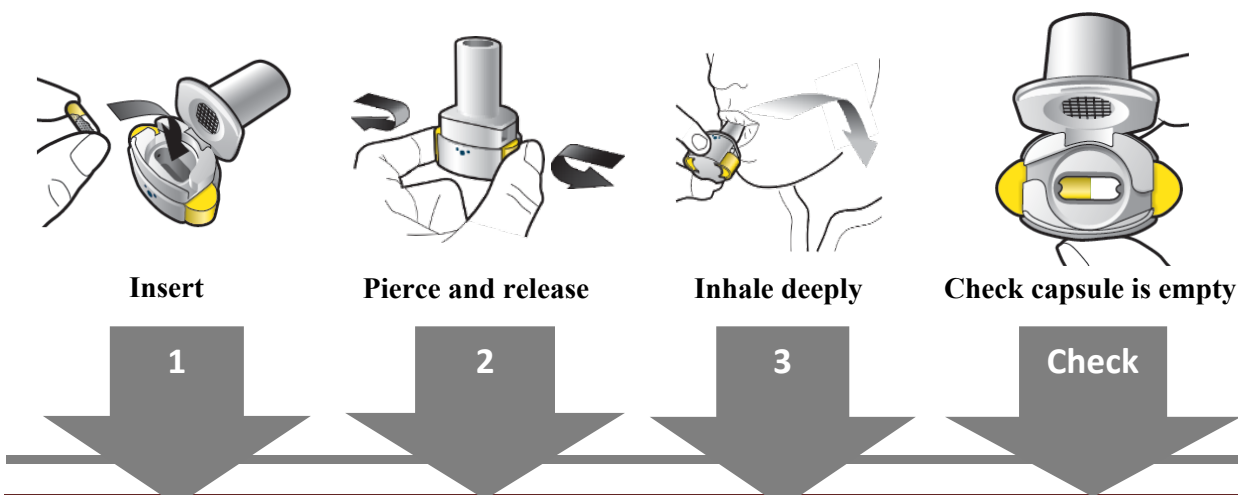
10/01/2022

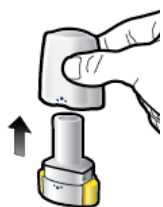
Serial Number

NPRA (R1/6) 07122021/244

Instructions for use of Ultibro Breezhaler inhaler

Please read the full Instruction for Use before using the Ultibro Breezhaler

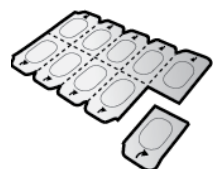




Step 1a:
Pull off cap



Step 1b:
Open inhaler



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 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.



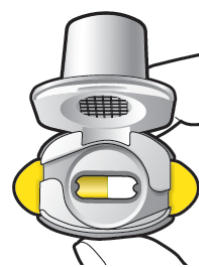
Step 3b:
Inhale medicine deeply
Hold the inhaler as shown in the picture. Place the mouthpiece in your mouth and close your lips firmly around it.

Do not press the side buttons.

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.



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



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

Close the inhaler and replace the cap.



Step 1d:

Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:

Close inhaler

Important Information

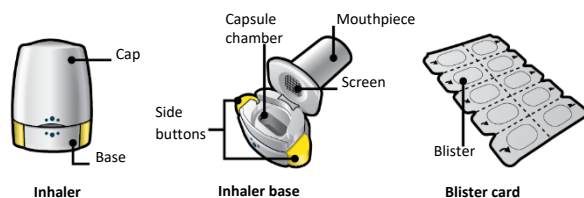
• **Ultibro Breezhaler**

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?

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.

	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.	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.
--	---	---