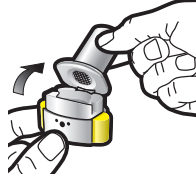
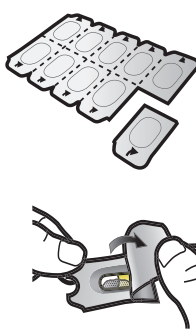
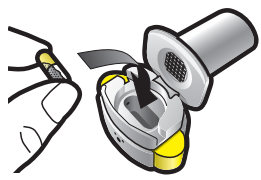
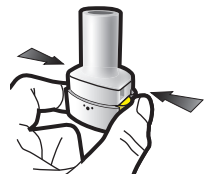
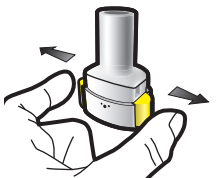
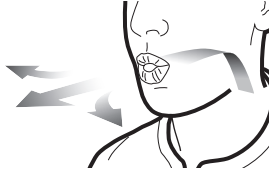
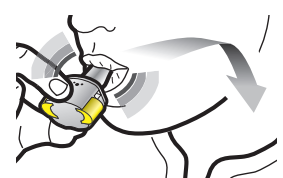
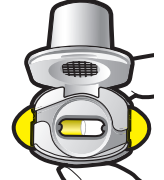
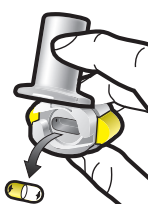


INSTRUCTIONS FOR USE OF THE ULTRIBRO BREEZHALER INHALER

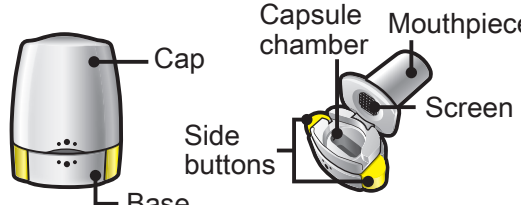
Please read the full set of **Instructions for Use** before using Ultibro Breezhaler.

Insert	Pierce and release	Inhale deeply	Check capsule is empty
1	2	3	Check
 Step 1a: Pull off cap  Step 1b: Open inhaler  Step 1c: Remove capsule Separate a part of the blister that contains one capsule, from the entire tray. Peel off the foil from the tray strip to take out the capsule. <u>Do not push the capsule out through the foil.</u> <u>Do not swallow the capsule.</u>  Step 1d: Insert capsule <u>Never place a capsule directly into the mouthpiece.</u>  Step 1e: Close inhaler	 Step 2a: Pierce capsule once Hold the inhaler upright. Pierce capsule by firmly pressing on both side buttons at the same time. You should hear a noise as the capsule is pierced. <u>Only pierce the capsule once.</u>  Step 2b: Release side buttons	 Step 3a: Breathe out fully <u>Do not blow into the inhaler.</u>  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. <u>Do not press the side buttons.</u> Breathe in quickly, as deeply as you can. During inhalation you will hear a whirring sound. 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.

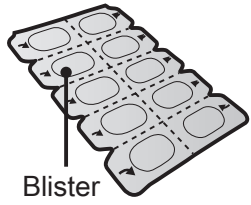
- Important Information
- Ultibro Breezhaler capsules must always be stored in the blister card and only removed immediately before use.
 - Do not push the capsule through the foil to remove it from the blister.
 - Do not swallow the capsule.
 - Do not use the Ultibro Breezhaler capsules with any other inhaler.
 - Do not use the Ultibro Breezhaler inhaler to take any other capsule medicine.
 - Never place the capsule in your mouth or into the mouthpiece of the inhaler.
 - Do not press the side buttons more than once.
 - Do not blow into the inhaler 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.

Each Ultibro Breezhaler Inhaler pack contains:

- One Ultibro Breezhaler inhaler
- One or more blisters, each containing 10 Ultibro Breezhaler capsules to be used in the inhaler



Inhaler Inhaler base



Blister

Frequently Asked Questions

Why didn't the inhaler make a noise when I inhaled the medicine?

The capsule may be stuck in the capsule chamber. If this happens, carefully loosen the capsule by tapping on 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 medicine. Close the inhaler and repeat steps 3a to 3c.

I coughed after inhaling the medicine. Does this matter?

This may happen. As long as the capsule is empty, you have received enough of the 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 increase 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 the inhaler with water.

Disposing of the inhaler after use

Dispose of the inhaler after 30 days of use.

Ask the pharmacist how to dispose of medicines and inhalers that are no longer required.

ULTIBRO® BREEZHALER® 110/50 mcg

Inhalation Powder hard capsules

Each capsule contains:
Indacaterol maleate 143 mcg (corresponds to indacaterol 110 mcg)
Glycopyrronium bromide 63 mcg (corresponds to glycopyrronium 50 mcg)

Each dose released by mouthpiece of the inhaler contains:
Indacaterol maleate 110 mcg (corresponds to indacaterol 85 mcg)
Glycopyrronium bromide 54 mcg (corresponds to glycopyrronium 43 mcg)
Inactive ingredients: see section 6 “Further information” and section 2 “Important information about some of the ingredients of the medicine”.

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to 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?

The medicine is used as maintenance bronchodilator treatment intended to relieve symptoms in adult patients suffering from 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.

Therapeutic group:

Medicines for obstructive airway diseases, adrenergics in combination with anticholinergics.

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

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to the active substances or to any of the other ingredients contained in the medicine listed in section 6 “Further information”.

Special warnings regarding use of the medicine:
Before treatment with Ultibro Breezhaler, tell the doctor, pharmacist or nurse if:

- You suffer from asthma – this medicine should not be used as a treatment for asthma.
- You suffer from heart problems.
- You suffer from epileptic fits.
- You suffer from thyroid gland problems (thyrotoxicosis).
- You suffer from diabetes.
- You are taking medicines for your lung disease which contain active substances similar (from the same class) to those in Ultibro Breezhaler (see section “If you are taking, or have recently taken, other medicines”).
- You suffer from kidney problems.
- You suffer from severe liver problems.
- You suffer from an eye problem called narrow-angle glaucoma.
- You suffer from difficulty passing urine.

During treatment with Ultibro Breezhaler:

Stop taking this medicine and seek medical help immediately if you experience one or more of the following:

- Eye pain or discomfort, temporary blurring of vision, if you see visual halos or colored images in combination 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 (urticaria) – these may be signs of an allergic reaction.
- Pressure in the chest, coughing, wheezing or breathlessness immediately after using the medicine – these may be signs of a condition called paradoxical bronchospasm.

Tell the 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

This medicine is not intended for use in children and adolescents under the age of 18 years since this medicine was not studied in this age group.

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:

- any medicine that may be similar to Ultibro Breezhaler (contains similar active substances).
- medicines called beta-blockers that may be used for treatment of 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 used for treatment of high blood pressure (such as hydrochlorothiazide)
 - medicines for breathing problems (methylxanthines such as theophylline)

Using the medicine and food

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

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 breast milk. Indacaterol, which is one of the active ingredients of the medicine, may prevent labor contractions due to its effect on the uterus.

If you are pregnant or breast-feeding, think you may be pregnant or are planning a pregnancy, consult with the doctor or pharmacist 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.

Important information about some of the ingredients of the medicine

The medicine contains lactose (23.5 mg in each capsule). If you have been told by the doctor that you have an intolerance to some sugars, refer to a doctor before using this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

How much medicine to use?

The dosage and treatment regimen will be determined by the doctor only. The usual dosage generally 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 exceed the recommended dose.

Use in elderly (age 75 and above)

If you are aged 75 and above, you can use this medicine at the same dosage as other adults.

When to inhale the medicine?

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

Ultibro Breezhaler can be inhaled at any time before or after consumption of food or drink.

How to inhale the medicine?

- Ultibro Breezhaler is intended for inhalation use.
- In this pack, you will find an inhaler and capsules (in blisters) that contain the medicine as powder for inhalation. 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 foil 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 after 30 days of use.
- Do not swallow the capsules.**
- Do not open and disperse the contents of the capsule. The powder in the capsules is intended for inhalation via the inhaler only.
- 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 an overdose or if a child or someone else accidentally used your capsules, proceed immediately to a doctor or a hospital emergency room. Bring the package of the medicine with you and show it. Medical attention may be needed. You may feel that your heart is beating faster than usual, or a headache, dizziness, nausea, a need to vomit, or you may experience visual disturbances, constipation or difficulty passing urine.

If you forget to take the medicine:

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

How long to continue treatment?

- Persist with the treatment as recommended by the doctor.
- 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 treatment with this medicine, consult the doctor or pharmacist.

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

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 further questions about the use of the medicine, consult the doctor, pharmacist or nurse.

4. SIDE EFFECTS

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

Stop using this medicine and seek medical help immediately if you experience any of the following serious side effects:

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

Difficulty breathing or swallowing, swelling of the tongue, lips or face, urticaria, skin rash – these may be signs of an allergic reaction.

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

Difficulty breathing with wheezing or coughing;
Eye pain or discomfort, temporary blurring of vision, if you see visual halos or colored images in combination with red eyes – these may be signs of glaucoma.
Swelling mainly of the tongue, lips, face and throat (possible signs of angioedema).

Refer to the doctor immediately if you experience any of the following serious side effects:

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

Feeling tired or very thirsty, having an increased appetite without gaining weight and passing more urine than usual – these may be signs of a high level of sugar in the blood (hyperglycemia).

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

Crushing chest pain with increased sweating – this may be a serious heart problem (ischemic heart disease);
Irregular heartbeat.

Additional side effects:

Very common side effects (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 side effects (may affect up to 1 in 10 people):

- 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.
- Stomach discomfort, indigestion.
- Dental caries.
- Difficulty and pain upon urination - these may be signs of bladder obstruction or urinary retention.
- Fever.
- Chest pain.

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

- Difficulty sleeping.
- Rapid heart rate.
- Palpitations - signs of irregular heart rate.
- Voice change (hoarseness).
- Nosebleeds.
- Diarrhea or stomachache.
- Dry mouth.
- Itching or rash.
- Pain that affects the muscles, ligaments, tendons, joints and bones.
- Muscle spasm.
- Muscle pain or tenderness.
- Pain in arms or legs.
- Swelling of the hands, ankles and feet.
- Tiredness.

Rare side effects (may affect up to 1 in 1,000 people):

- Tingling or numbness.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this 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) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the 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 at a temperature above 25°C. Store in the original packaging in order to protect from moisture.
- Do not remove the capsules from the blister until immediately before use.
- Dispose of the inhaler after 30 days of use.
- Do not use the medicine if you notice that the package is damaged or shows signs of tampering.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Capsule fill:

Lactose monohydrate/hydrate, magnesium stearate.

Capsule shell components:

Hypromellose, purified water, carrageenan, potassium chloride, FD&C Yellow 5/Tartrazine (E102, CI 19140), printing ink black and blue.

Black ink imprinted on the capsule cap:

Shellac; ethyl alcohol, anhydrous; isopropyl alcohol; propylene glycol; N-butyl alcohol; ammonium hydroxide; potassium hydroxide; purified water; iron oxide, black (E172, CI 77499).

Blue ink imprinted on the capsule body:

Shellac; ethyl alcohol, anhydrous; FD&C Blue 2/Indigo carmine aluminum lake (E132, CI 73015); N-butyl alcohol; titanium dioxide; propylene glycol; isopropyl alcohol.

What the medicine looks like and the contents of the package:

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

The capsules have a transparent yellow cap and natural transparent body. They contain a white to almost white powder, with the product code “IGP110.50” printed in blue under two blue bars on the capsule body and the company logo (⚡) printed in black on the cap.
Pack size: 30 capsules + 1 inhaler.

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

Revised in January 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 151 39 33990