

ULTIBRO® BREEZHALER® 110/50

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ULTIBRO BREEZHALER?

ULTIBRO BREEZHALER contains the active ingredients indacaterol and glycopyrronium bromide (glycopyrrolate). ULTIBRO BREEZHALER is used to treat chronic obstructive pulmonary disease. This is a serious lung condition caused by damage to the lungs. For more information, see Section [1. Why am I using ULTIBRO BREEZHALER?](#) in the full CMI.

2. What should I know before I use ULTIBRO BREEZHALER?

Do not use if you have ever had an allergic reaction to ULTIBRO BREEZHALER or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ULTIBRO BREEZHALER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ULTIBRO BREEZHALER and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ULTIBRO BREEZHALER?

- Your doctor will decide which dose is appropriate for you
- Inhale the contents of one capsule once daily.
- Do not take more than one dose in a day.

More instructions can be found in Section [4. How do I use ULTIBRO BREEZHALER?](#) in the full CMI.

5. What should I know while using ULTIBRO BREEZHALER?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you
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	<p>are using ULTIBRO BREEZHALER.</p> <ul style="list-style-type: none"> • Use this medicine exactly as prescribed by your doctor or pharmacist. • Tell your doctor immediately if you experience difficulties in breathing.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not use this medicine to treat any other problems unless your doctor tells you to. • Do not swallow ULTIBRO BREEZHALER capsules.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how ULTIBRO BREEZHALER affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.

Looking after your medicine	<ul style="list-style-type: none"> • Do not store above 25°C. • The capsules must always be stored in the blister pack to protect them from moisture and light.
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For more information, see Section [5. What should I know while using ULTIBRO BREEZHALER?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include headache, dizziness, dry mouth, fever, indigestion, blocked nose, difficulty in swallowing, throat irritation, cough, pain in muscles, bones, joints, pain in arms or legs. Serious side effects include difficulty in breathing or swallowing, swelling of tongue, lips and face, skin rash, itching and hives, difficulty breathing with wheezing or coughing, fast or irregular heart beats, chest pain, eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes, frequent urination, difficulty passing urine or painful urination.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ULTIBRO® BREEZHALER® 110/50

Active ingredients: *Indacaterol/ Glycopyrronium bromide (glycopyrrolate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ULTIBRO BREEZHALER. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ULTIBRO BREEZHALER.**

Where to find information in this leaflet:

- [1. Why am I using ULTIBRO BREEZHALER?](#)
- [2. What should I know before I use ULTIBRO BREEZHALER?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ULTIBRO BREEZHALER?](#)
- [5. What should I know while using ULTIBRO BREEZHALER?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ULTIBRO BREEZHALER?

ULTIBRO BREEZHALER contains the active ingredients indacaterol and glycopyrronium bromide (glycopyrrolate). ULTIBRO BREEZHALER belongs to a

group of medicines called bronchodilators. They help to relax the muscles around your airways in the lungs and keep them open. This makes breathing easier.

ULTIBRO BREEZHALER is used to treat chronic obstructive pulmonary disease (COPD). It is a serious lung condition caused due to damage to the lungs. The damage results in irritation and swelling inside the airways. This limits the airflow into and out of the lungs. ULTIBRO BREEZHALER helps improve and reduce symptom flare-ups from occurring.

2. What should I know before I use ULTIBRO BREEZHALER?

Warnings

Do not use ULTIBRO BREEZHALER if:

- you are allergic to indacaterol and glycopyrronium bromide (glycopyrrolate), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction include difficulty in breathing or swallowing, swelling of the tongue, lips, face, other parts of the body, hives and skin rash.

Check with your doctor if you:

- have asthma
- have any heart problems

- have any thyroid gland problems
- have diabetes
- are taking similar medicines for your lung disease
- have any kidney problems
- have any liver problems
- have an eye problem including narrow-angle glaucoma
- have difficulty passing urine

Do not give this medicine to a child or adolescent under 18 years of age.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

ULTIBRO BREEZHALER is not recommended for use during pregnancy.

Your doctor will advise you regarding the possible risks and benefits of using ULTIBRO BREEZHALER during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is unknown whether the active ingredients in ULTIBRO BREEZHALER passes into breast milk.

Your doctor will advise you regarding the possible risks and benefits of using ULTIBRO BREEZHALER during breast feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ULTIBRO BREEZHALER and affect how it works.

Tell your doctor or pharmacist if you take any of the following:

- medicines used in the treatment of depression
- any other medicines for your lung disease. Use of these may increase the risk of experiencing possible side effects
- medicines that decrease the level of potassium in your blood
- medicines for high blood pressure and heart problems or in the treatment of glaucoma

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ULTIBRO BREEZHALER.

4. How do I use ULTIBRO BREEZHALER?

How much to use

- Your doctor will decide which dose is appropriate for you.
- The dose for adults is inhaling the contents of one capsule once daily.
- Follow the instructions provided and use ULTIBRO BREEZHALER until your doctor tells you to stop.
- **Do not take more than one dose in a day.**
- **Ask your doctor if you do not understand your dose.**

When to use ULTIBRO BREEZHALER

ULTIBRO BREEZHALER should be used at about the same time each day.

How to use ULTIBRO BREEZHALER

- Carefully read the instructions and follow the diagrams inside the carton that show you how to use the BREEZHALER properly.
- Use ULTIBRO capsules only for oral inhalation using BREEZHALER inhaler.
- **Do not swallow ULTIBRO BREEZHALER capsules.**
- Keep the capsules in the blister pack and only remove them before using.

- Peel the backing away from the blister pack to open it; do not push the capsule through the foil.
- **If you do not understand how to use the inhaler, ask your doctor or pharmacist for advice.**

If you forget to use ULTIBRO BREEZHALER

ULTIBRO BREEZHALER should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much ULTIBRO BREEZHALER

If you think that you have used too much ULTIBRO BREEZHALER you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ULTIBRO BREEZHALER?

Things you should do

Call your doctor straight away if you:

- develop any allergic reaction to ULTIBRO BREEZHALER
- are pregnant or intend to become pregnant.
- experience any contraction in the airways causing difficulty in breathing.
- have any difficulty passing urine.
- have any heart issues including pain or rapid heartbeat.
- experience eye pain, discomfort or temporary blurring of vision.

Remind any doctor, dentist or pharmacist you visit that you are using ULTIBRO BREEZHALER.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not swallow ULTIBRO BREEZHALER capsules.
- Do not use this medicine to treat any other problems unless your doctor tells you to.
- Do not take more than one dose in a day.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ULTIBRO BREEZHALER affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Follow the instructions provided in the user leaflet on how to properly clean and take care of your ULTIBRO BREEZHALER
- Store below 25°C
- Always store ULTIBRO BREEZHALER capsules in the blister pack to protect from moisture.
- Remove the capsules only before use.
- Dispose of each BREEZHALER inhaler after 30 days of use.

Follow the instructions in the carton on how to take care of your medicine properly.

Store in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Discard your ULTIBRO BREEZHALER when you have no capsules left.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General problems: <ul style="list-style-type: none">• Headache• Dizziness• Dry mouth• Fever• Indigestion Respiratory problems:	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • Blocked nose • Difficulty in swallowing • Throat irritation • Cough <p>Muscle problems:</p> <ul style="list-style-type: none"> • Pain in muscles, bones, joints • Pain in arms or legs 	

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • Difficulty in breathing or swallowing, swelling of tongue, lips and face, skin rash, itching and hives • Difficulty breathing with wheezing or coughing <p>Heart problems:</p> <ul style="list-style-type: none"> • Fast or irregular heart beats • Chest pain 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Eye problems:</p> <ul style="list-style-type: none"> • 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. <p>Other problems:</p> <ul style="list-style-type: none"> • Excessive thirst or hunger and frequent urination (symptoms of high blood sugar levels) • Difficulty passing urine or painful urination 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ULTIBRO BREEZHALER contains

Active ingredient (main ingredient)	Indacaterol and glycopyrronium bromide (glycopyrrolate)
Other ingredients (inactive ingredients)	Capsule fill: Lactose monohydrate, magnesium stearate. Capsule shell components: Hypromellose, purified water, carrageenan, potassium chloride, CI Food Yellow 4/Tartrazine. Black Printing Ink: Shellac, ethyl alcohol, isopropyl alcohol, propylene glycol, n-butyl alcohol, ammonium

	hydroxide, potassium hydroxide, water purified, iron oxide black Blue Printing Ink: Shellac, ethyl alcohol, FD&C Blue 2, n-butyl alcohol, titanium dioxide, propylene glycol, isopropyl alcohol
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What ULTIBRO BREEZHALER looks like

Inhalation powder, hard capsule

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 the body and the company logo printed in black on the cap (AUST R 206449).

Breezhaler

A white plastic BREEZHALER inhalation device is also supplied in the pack.

Who distributes ULTIBRO BREEZHALER

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

® = Registered Trademark

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