

ONBREZ® BREEZHALER®

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 ONBREZ BREEZHALER?

ONBREZ BREEZHALER contains the active ingredient indacaterol maleate. ONBREZ BREEZHALER is used to treat chronic obstructive pulmonary disease. It is a serious lung condition caused by damage to the lungs.

For more information, see Section [1. Why am I using ONBREZ BREEZHALER?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to ONBREZ 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 ONBREZ BREEZHALER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ONBREZ 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 ONBREZ BREEZHALER?

- Your doctor will advise you of the appropriate dose.
- Inhale the contents of one capsule once daily.

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

5. What should I know while using ONBREZ BREEZHALER?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ONBREZ BREEZHALER.

	<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 ONBREZ 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 ONBREZ 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 30°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 ONBREZ BREEZHALER?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include dry mouth, headache, dizziness, fatigue, unusual weakness, numbness, muscle cramps, muscle pain, muscle tenderness or weakness not caused by exercise, pain in bones, muscles and joints, swelling of ankles, feet or hands, rash, itching, blocked nose, runny nose, sneezing, cough, difficulty in swallowing. 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 heartbeat, chest pain, excessive thirst or hunger and frequent urination and 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.

ONBREZ® BREEZHALER®

Active ingredient: indacaterol maleate

Consumer Medicine Information (CMI)

This leaflet provides important information about using ONBREZ 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 ONBREZ BREEZHALER.**

Where to find information in this leaflet:

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

1. Why am I using ONBREZ BREEZHALER?

ONBREZ BREEZHALER contains the active ingredient indacaterol maleate. ONBREZ 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, making breathing easier.

ONBREZ 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. COPD symptoms include shortness of breath, cough that brings up mucus and chest discomfort.

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

Warnings

Do not use ONBREZ BREEZHALER if:

- you are allergic to indacaterol maleate, 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 difficulties in breathing or swallowing, swelling of tongue, lips, face, other parts of the body, hives and skin rash.

Check with your doctor if you:

- have asthma
- have heart problems

- have epilepsy
- have thyroid gland problems
- have diabetes

Do not use ONBREZ BREEZHALER in patients below 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.

ONBREZ BREEZHALER is not recommended for use during pregnancy.

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

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

It is unknown whether the active ingredients in ONBREZ BREEZHALER pass into breast milk.

Your doctor will advise you regarding the possible risks and benefits of using ONBREZ 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 ONBREZ BREEZHALER and affect how it works.

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

- any other medicines for your lung disease. Use of these may increase the risk of experiencing possible side effects
- medicines for high blood pressure and heart problems (beta blockers e.g. propranolol)
- medicines used to treat depression and other mental disorders (e.g. tricyclic antidepressants, monoamine oxidase inhibitors)
- medicines for glaucoma, including eye drops (e.g. timolol)
- medicines that decrease the level of potassium in the blood
- medicines for hay fever, coughs, colds and runny nose
- other medicines used for breathing problems such as methylxanthines (e.g. theophylline) or steroids (e.g. prednisolone)

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

4. How do I use ONBREZ BREEZHALER?

How much to take

- Your doctor will decide which dose is appropriate for you.
- Inhale the contents of one capsule once daily.
- Follow the instructions provided and use ONBREZ BREEZHALER until your doctor tells you to stop.
- **Ask your doctor if you do not understand your dose.**

When to use ONBREZ BREEZHALER

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

How to use ONBREZ BREEZHALER

- Carefully read the instructions and follow the diagrams inside the carton that show you how to use the BREEZHALER properly.
- Use ONBREZ capsules only for oral inhalation using the BREEZHALER inhaler.
- **Do not swallow the ONBREZ BREEZHALER capsules.**

- Keep the capsules in the blister pack and only remove them before using them.
- 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 ONBREZ BREEZHALER

ONBREZ BREEZHALER should be used regularly at the same time each day. If you miss your dose at the usual time, take the next dose at the usual time the next day.

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 ONBREZ BREEZHALER

If you think that you have used too much ONBREZ 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 ONBREZ BREEZHALER?

Things you should do

Call your doctor straight away if you:

- develop any allergic reaction to ONBREZ BREEZHALER.
- are pregnant or intend to become pregnant.
- experience any contraction in the airways causing difficulty in breathing.
- experience chest pains or heart issues.

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

Things you should not do

- Do not stop using this medicine suddenly.
- Do not swallow ONBREZ 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 ONBREZ 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 ONBREZ BREEZHALER
- Store below 30°C
- Always store ONBREZ BREEZHALER capsules in the blister pack to protect them 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 it 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 ONBREZ 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
<p>General problems:</p> <ul style="list-style-type: none">• Dry mouth• Headache• Dizziness• Fatigue• Unusual weakness• Numbness <p>Muscle problems:</p> <ul style="list-style-type: none">• Muscle cramps• Muscle pain, muscle tenderness or weakness, not caused by exercise	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● Pain in bones, muscles and joints. ● Swelling on ankles, feet or hands <p>Skin problems:</p> <ul style="list-style-type: none"> ● Rash ● Itching <p>Respiratory problems:</p> <ul style="list-style-type: none"> ● Blocked nose, runny nose, sneezing ● Cough ● Difficulty in swallowing 	

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>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>Heart problems:</p> <ul style="list-style-type: none"> ● Fast or irregular heartbeat ● Chest pain <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 ONBREZ BREEZHALER contains

Active ingredient (main ingredient)	Indacaterol maleate
Other ingredients (inactive ingredients)	Lactose monohydrate and gelatin.
Potential allergens	Lactose monohydrate and gelatin.

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

What ONBREZ BREEZHALER looks like

ONBREZ BREEZHALER is a hard capsule containing powder for oral inhalation. It is available in 2 strengths. A white plastic Breezhaler inhalation device is also supplied in the pack.

150 micrograms

Black product code "IDL 150" printed above and black company logo printed under black bar on clear colourless hard capsule (AUST R 160172).

300 micrograms

Blue product code "IDL 300" printed above and blue company logo printed under blue bar on clear colourless hard capsule (AUST R 160177).

Who distributes ONBREZ BREEZHALER

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1-800-671-203

Web site: www.novartis.com.au

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