

ONBREZ[®]

BREEZHALER[®]

capsules for inhalation

Indacaterol maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Onbrez Breezhaler.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Onbrez Breezhaler against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Onbrez Breezhaler is used for

Onbrez capsules are for the treatment of chronic obstructive pulmonary disease, also called COPD. COPD is a serious lung condition that can cause difficulty in breathing, and constant coughing. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up phlegm.

Onbrez capsules for inhalation belong to a group of medicines called bronchodilators. These medicines are used to keep the air passages in the lungs open and make breathing easier.

Onbrez capsules make breathing easier by opening the small air passages in the lungs and helping them to remain relaxed and open.

Onbrez is a long acting bronchodilator. Each dose of Onbrez will keep your air passages open and relieve chest tightness and wheezing for 24 hours.

Onbrez capsules for inhalation contain the active ingredient, indacaterol maleate in a capsule form.

The capsules are for oral inhalation only. The powder from the capsule is inhaled (breathed into the lungs), using the Breezhaler[®] inhalation device provided with the medicine.

Ask your doctor if you have any questions about why Onbrez Breezhaler has been prescribed for you.

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

It is not addictive.

Before you use Onbrez Breezhaler

When you must not use it

Onbrez Breezhaler is not suitable for use in the treatment of asthma. Onbrez Breezhaler is not suitable for people who have both asthma and COPD.

Its use may lead to an overdose of bronchodilator medication, commonly found in asthma medications.

Do not use Onbrez Breezhaler if you have ever had an allergic reaction to indacaterol maleate (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not breast-feed while you are using this medicine.

It is not known if the active ingredient passes into the breast milk and could affect your baby.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to use it

Tell your doctor if you have any of the following medical conditions:

- asthma
- heart problems
- epilepsy
- thyroid gland problems
- diabetes

Your doctor may want to take special precautions if you have any of the above conditions.

Tell your doctor if you are pregnant or intend to become pregnant.

Onbrez is not recommended for use during pregnancy. If it is necessary for you to use this medicine during pregnancy, your doctor will discuss with you the benefits and risks involved.

Taking other medicines

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

Some medicines and Onbrez may interfere with each other. These include:

- some similar medicines used to treat your lung disease
- 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 bronchodilators used for breathing problems such as methylxanthines (e.g. theophylline) or steroids (e.g. prednisolone)
- diuretic medicines, also called fluid or water pills used to treat high blood pressure (e.g. hydrochlorothiazide) or other heart problems (e.g. propranolol)

You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start using Onbrez Breezhaler.

How to use Onbrez Breezhaler

You may have been given a treatment plan by your doctor to help you manage your COPD and to know what to do when it worsens. Make sure that you understand this plan by talking to your doctor and pharmacist about it. In particular, do not stop other medications that are used to treat COPD even if you feel well. Only stop other prescribed medications on medical advice.

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label or in the carton, ask your doctor or pharmacist for help.

How much to use

The usual dose for adults is the inhalation (puff) of the content of one capsule each day, every day. Only two daily doses are possible, 150 or 300 micrograms. There is no gain to be had from exceeding these doses. Most people with COPD benefit from 150 micrograms per day.

Take your puff at the same time each day to help minimise your symptoms throughout the day and night. It will also help you remember to use your medicine.

How to use the Breezhaler

Carefully read the instructions and follow the diagrams inside the carton that show you how to use the Breezhaler properly.

Make sure you understand how to use the device properly. If you are not sure, ask your doctor or pharmacist for help.

How long to use it

Continue to use this medicine for as long as your doctor tells you to.

If it helps your breathing problems, your doctor may want you to keep using it for a long time. This medicine helps to control your condition but it does not cure it. You will need to use other medications as well and this will be outlined in your COPD management plan.

If you still smoke, you should stop. If you have not taken advice about an exercise program, consider asking for it.

If you forget to use it

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

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

Do not use a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much Onbrez. Do this even if there are no signs of discomfort or poisoning.

Some of the symptoms of an overdose may include nausea (feeling sick), vomiting, shakiness, sleepiness, headache and fast or irregular heartbeat.

While you are using Onbrez Breezhaler

Things you must do

Only use the inhalation device contained in this pack.

Use this medicine exactly as your doctor has prescribed. Try not to miss any doses and use it even if you feel well.

If you do not follow your doctor's instructions, you may not get relief from your breathing problems or you may have unwanted side effects.

If you find that the usual dose of Onbrez Breezhaler is not giving as much relief as before, or does not last as long as usual, contact your doctor so that your condition can be checked.

This is important to ensure your COPD is controlled properly.

If you become pregnant while using this medicine, tell your doctor.

Your doctor can discuss with you the risks of using it while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Onbrez Breezhaler.

Tell any other doctor, dentist or pharmacist who treats you that you are using this medicine.

Things you must not do

Do not exceed the recommended daily dose - it will not help you to do this. Instead, check your COPD management plan and seek medical attention. Do not swallow the capsules.

Do not take any other medicines for your breathing problems without checking with your doctor.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Onbrez affects you.

This medicine may cause dizziness in some people. Make sure you know how you react before you drive a car, operate machinery, or do anything else that could be dangerous. If you are dizzy, do not drive.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Onbrez Breezhaler.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- combination of sore throat, runny nose, blocked nose, sneezing, coughing, headache with or without fever
- sneezing
- muscle pain
- muscle spasm
- swollen hands, ankles and feet
- crushing chest pain (heart problems)
- neck pain
- palpitations (feeling that your heartbeat is unusually fast or irregular)
- headache
- sore throat
- cough
- runny nose
- blocked nose
- dry mouth
- feeling pressure or pain in the cheeks and forehead (inflammation of the sinuses)
- chest pain
- chest discomfort
- pain in muscles, bones or joints
- excessive thirst, high urine output, increase appetite with weight loss and tiredness, high level of sugar in the blood (that are signs of a disease called diabetes)
- tingling and numbness
- dizziness
- vertigo

Some people occasionally cough soon after inhaling the medicine. Cough is a common symptom in COPD patients. If you experience coughing briefly after inhaling the medicine, do not worry, as long as

the capsule is empty, you have received the full dose.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- crushing chest pain (heart problems)
- you develop signs of allergy such as swelling of the face, lips, tongue or other part of the body; severe dizziness or fainting; redness, itching or rash on the skin

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects may only be found when your doctor orders blood tests from time to time.

After using Onbrez Breezhaler

Cleaning and storage

- Follow the instructions in the carton on how to properly clean and take care of your Onbrez Breezhaler.
- Store it in a cool dry place away from moisture.
- Do not store the device or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep this medicine where children cannot see or reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist how to dispose of it properly.

Product description

What it looks like

Indacaterol 150 microgram capsules

Clear colourless hard capsules with black imprints. The capsules are marked with "IDL 150" and a Novartis logo. The capsules come in foil packs containing 30 capsules in a cardboard carton.

Indacaterol 300 microgram capsules

Clear colourless hard capsules with blue imprints. The capsules are marked with "IDL 300" and a Novartis logo. The capsules come in foil packs containing 30 capsules in a cardboard carton.

Breezhaler

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

Ingredients

Active Ingredient

Each capsule contains either 150 or 300 micrograms of indacaterol as indacaterol maleate.

Inactive ingredients

Onbrez capsules also contain lactose. The capsule shell is made of gelatin, an edible material.

Sponsor

Onbrez Breezhaler is supplied in Australia by: 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

Onbrez Breezhaler is supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

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