

Good to know about
Ultibro[®] Breezhaler[®]

Medicine for the Treatment of Chronic Obstructive
Pulmonary Disease (COPD)

Information for those who
have been prescribed Ultibro



For further information read the package insert or visit www.fass.se

It is estimated that approx. 400 000-700 000 Swedes currently have COPD, but the incidence is increasing. Approx. 2 700 people die from the disease each year.



Content

What is Ultibro Breezhaler?	4
What is COPD?	7
How to use your Ultibro Breezhaler inhaler	11
Important to remember when using Ultibro Breezhaler	14
Video instructions on the Internet	15

What is Ultibro Breezhaler?

Ultibro Breezhaler is a medicine that contains the active substances indacaterol and glycopyrronium. It is used to alleviate the symptoms of chronic obstructive pulmonary disease (COPD) in adults.

Read more about COPD on page 6.

How to take the medicine

The medicine is inhaled by means of an inhaler. Place a capsule with the medicine in the supplied inhaler and then inhale the medicine. See page 11 for instructions on how to use the Ultibro Breezhaler inhaler.

Dose

The recommended dose is one capsule inhaled once daily - at the same time each day. Please follow the instructions given to you by your doctor.

If you forget to take a dose

Take the recommended dose as soon as possible.



Never inhale a double dose or two doses on the same day!

Contact your doctor immediately if you take more than the recommended dose!

Packs

The Ultibro Breezhaler inhaler is supplied in packs containing both the Ultibro Breezhaler inhaler and Ultibro Breezhaler capsules.



Currently available in Sweden:

- Packs of 30x1 capsules and 1 Ultibro Breezhaler inhaler.
- Single pack containing 30x1 or 90x1 capsules and 1 Ultibro Breezhaler inhaler.

The most important thing you can do to slow the progression of the disease is to stop smoking.



What is COPD?

COPD stands for Chronic Obstructive Pulmonary Disease, which is a chronic disorder that reduces lung function. The ability to breathe deteriorates due to the airways narrowing owing to chronic inflammation and destruction of the lung tissue.

COPD cannot be cured, but you can treat the symptoms and use preventive treatment to prevent them from getting worse. In that way, the disease becomes easier to live with.

COPD is often detected around the age of 50-60 years, but for some people, the first signs may already appear around the age of 35-40 years.

Causes of COPD

The most common cause is smoking. At least 85% of all COPD patients are smokers or former smokers. In patients who have never smoked, the disorder may be caused by prolonged and considerable exposure to dust associated with working in e.g. the cement industry. The disease can also be caused by air pollution or passive smoking. If you are a smoker, the most important thing you can do to slow the progression of the disease, is to stop smoking.

What are the symptoms of COPD?

COPD develops insidiously over many years. Lung function gradually decreases and it becomes harder to breathe. In the beginning the symptoms are only felt upon exertion, e.g. when walking up the stairs. Often the person developing COPD gets used to the reduced lung function and therefore does not seek the advice of a doctor.

Common signs of COPD are:

- shortness of breath
- frequent need to cough up phlegm
- frequent respiratory tract infections

The increasing shortness of breath during physical activity is often interpreted as a natural sign of getting older.

How is the diagnosis of COPD made?

The diagnosis is made by means of a lung function test called spirometry. Spirometry measures how much air you can blow and how fast it comes out.

COPD patients have narrowing and less elastic lung tissue and therefore they have a more difficult time emptying their lungs than normal. From the lung function test, the doctor is able to determine whether you have COPD. What the lung function is compared to the expected value can also be calculated. In some cases, the doctor may also want to take e.g. a blood test, an X-ray of the lungs or perform an ECG. This may be used to rule out other diseases or to ensure the right treatment is given.

If you have been diagnosed with COPD you should see your healthcare provider for follow-ups regarding your care and treatment at least once annually.

Would you like to learn more?

Please contact the following organisations if you require more information about COPD.

The Swedish Heart-Lung Foundation

www.hjart-lung.se

Tel.: +46 (0)8-55 606 200

The Swedish medical advisory service

www.1177.se

Enter COPD in the search field

Tel.: 1177 [in Sweden]

Sluta-Röka-Linjen helpline support www.slutarokalinjen.org

Tel.: +46 (0)20-84 00 00

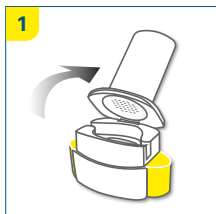


The vast majority of COPD patients feel better from doing physical activity and exercise. Speak to your doctor about what may benefit you most.



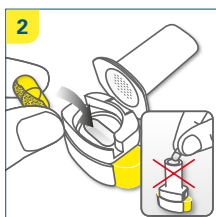
How to use your Ultibro Breezhaler inhaler

! Please read the package insert for further information.



Open the inhaler:

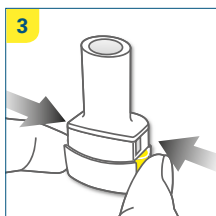
- Firmly grip the base of the inhaler and tilt the mouthpiece.
- The inhaler is now open.



Insert the capsule:

- Place the capsule into the capsule chamber.

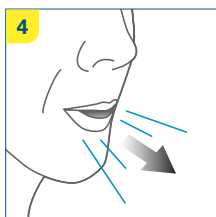
Never place a capsule directly into the mouthpiece.



Perforate the capsule:

- Hold the inhaler upright with the mouthpiece upwards.
- Perforate the capsule by simultaneously pressing both side buttons hard together in one steady movement. **This should only be done once.**

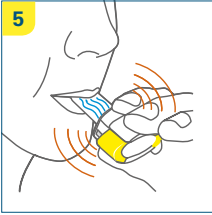
- You will hear a **click** as the capsule is perforated.



Exhale:

- Take a deep breath before putting the mouthpiece in your mouth.

Do not blow into the mouthpiece.



Inhale the medicine:

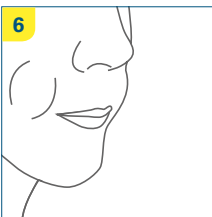
- Do the following in order to inhale the medicine deeply into your lungs:
- Hold the inhaler as shown in the picture. The side buttons should be facing left and right, respectively. Do not press the side buttons.
- Place the mouthpiece in your mouth and close your lips firmly around it.
- Breathe in rapidly but steadily and as deeply as you can. **Do not press the side buttons.**

NOTE!

As you breathe in through the inhaler, the capsule spins around in the chamber and you should hear a whirring sound. Once the medicine reaches your lungs, you will experience a sweet flavour.

If you do not hear a whirring sound:

- The capsule may be stuck in the capsule chamber. If this should happen:
- Open the inhaler and carefully loosen the capsule by tapping the base of the inhaler. Do not press the side buttons.
- Inhale the medicine again according to steps 4 and 5, above.



Hold your breath:

When you have inhaled the medicine:

- Hold your breath for at least 5-10 seconds or as long as you can while removing the inhaler from your mouth.
- Thereafter, exhale.
- Open the inhaler to see whether there is any remaining powder in the capsule.
- If there is still powder in the capsule:
- Close the inhaler.
- Repeat steps 5 and 6.

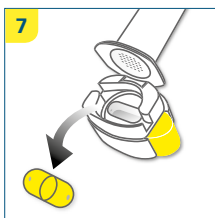
Most people empty the capsule with one or two inhalations.

COPD patients do better if they get lots of fresh air, and exercise or sports - to the extent they are able to do so - can have a positive contribution on well-being and quality of life.



Additional information

Some people may occasionally cough soon after inhaling the medicine. Do not worry if this happens. As long as the capsule is empty, you have received enough of your medicine.



When you have inhaled your daily dose of Ultibro Breezhaler:

- Open the mouthpiece again, and remove the empty capsule by tipping it out of the capsule chamber. Discard the capsule with the household waste.
- Close the inhaler and replace the cap.

Do not store capsules which have not yet been perforated in the inhaler.



Read the package insert carefully before you start using the Ultibro Breezhaler.

Important to remember when using Ultibro Breezhaler

- Do not use the capsules with any other inhaler, and do not use the Ultibro Breezhaler inhaler to take any other medicine capsules.
- When you start a new pack, use the new inhaler that is in the pack.
- You can discard your Breezhaler inhaler with your household waste or in the plastic recycling. It is made of recycled plastic.
- If you experience side effects when using Ultibro Breezhaler please contact your doctor immediately.
- The capsules must never be swallowed - the powder in the capsules must be inhaled using the Ultibro Breezhaler inhaler.

Cleaning

- Clean the inhaler by wiping the mouthpiece in and outside with a clean, dry, lint-free cloth to remove any residual powder.
- Never wash the inhaler with water.
- Keep the inhaler dry.
- Never take the inhaler apart.

Find out how to use the

Ultibro Breezhaler inhaler online at:

www.medicininstruktioner.se/Product.asp?ProductId=290



When you start a new pack, use the new inhaler that is in the pack and discard the old one.

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