

Package leaflet: Information for the user

Seebri® Breezhaler® 44 micrograms inhalation powder, hard capsules glycopyrronium (as glycopyrronium bromide)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Seebri Breezhaler is and what it is used for
2. What you need to know before you use Seebri Breezhaler
3. How to use Seebri Breezhaler
4. Possible side effects
5. How to store Seebri Breezhaler
6. Contents of the pack and other information

1. What Seebri Breezhaler is and what it is used for

What Seebri Breezhaler is

This medicine contains an active substance called glycopyrronium bromide. This belongs to a group of medicines called bronchodilators.

What Seebri Breezhaler is used for

This medicine is used to make breathing easier for adult patients who have breathing difficulties due to 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.

2. What you need to know before you use Seebri Breezhaler

Do not use Seebri Breezhaler

- if you are allergic to glycopyrronium bromide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using Seebri Breezhaler, if any of the following applies to you:

- you have kidney problems.
- you have an eye problem called narrow-angle glaucoma.
- you have difficulty passing urine.

During treatment with Seebri Breezhaler, stop taking this medicine and tell your doctor immediately:

- if you experience tightness of the chest, coughing, wheezing or breathlessness immediately after using Seebri Breezhaler (signs of bronchospasm).
- if you experience difficulties in breathing or swallowing, swelling of the tongue, lips or face, skin rash, itching and hives (signs of allergic reaction).
- if you experience 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.

Seebri Breezhaler is used as a maintenance treatment for your COPD. Do not use this medicine to treat a sudden attack of breathlessness or wheezing.

Children and adolescents

Do not give this medicine to children or adolescents below the age of 18 years.

Other medicines and Seebri Breezhaler

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines similar to Seebri Breezhaler used for your lung disease, such as ipratropium, oxitropium or tiotropium (so called anticholinergics).

No specific side effects have been reported when Seebri Breezhaler has been used together with other medicines used to treat COPD such as reliever inhalers (e.g. salbutamol), methylxanthines (e.g. theophylline) and/or oral and inhaled steroids (e.g. prednisolone).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There are no data from the use of this medicine in pregnant women and it is not known whether the active substance of this medicine passes into human milk.

Driving and using machines

It is unlikely that this medicine will affect your ability to drive and use machines.

Seebri Breezhaler contains lactose

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to use Seebri Breezhaler

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Seebri Breezhaler to use

The usual dose 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 use more than your doctor tells you to use.

Elderly people

You can use this medicine if you are aged 75 years and over at the same dose as for other adults.

When to inhale Seebri Breezhaler

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

You can inhale this medicine any time before or after food or drink.

How to inhale Seebri Breezhaler

- In this pack, you will find an inhaler and capsules (in blisters) that contain the medicine as inhalation powder. Only use the capsules with the inhaler provided in this pack (Seebri Breezhaler inhaler). The capsules should remain in the blister until you need to use them.
- Do not push the capsule through the foil.
- When you start a new pack, use the new Seebri Breezhaler inhaler that is supplied in the pack.
- Dispose of each inhaler after all capsules in that pack have been used.
- Do not swallow the capsules.
- Please read the instructions at the end of this leaflet for more information on how to use the inhaler.

If you use more Seebri Breezhaler than you should

If you have inhaled too much of this medicine or if someone else accidentally uses your capsules, you must immediately either tell your doctor or go to the nearest emergency unit. Show the pack of Seebri Breezhaler. Medical attention may be needed.

If you forget to use Seebri Breezhaler

If you forget to inhale a dose, take one as soon as possible. However, do not take two doses on the same day. Then take the next dose as usual.

How long to continue your treatment with Seebri Breezhaler

- Keep using this medicine for as long as your doctor tells you.
- COPD is a long-term disease and you should use this medicine every day and not only when you have breathing problems or other symptoms of COPD.

If you have questions about how long to continue your treatment with this medicine, talk to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects may be serious but are uncommon

(may affect up to 1 in 100 people)

- Irregular heart beat
- High level of blood sugar (hyperglycaemia: typical symptoms include excessive thirst or hunger and frequent urination)
- Rash, itching, hives, difficulty breathing or swallowing, dizziness (possible signs of allergic reaction)
- Swelling mainly of the tongue, lips, face or throat (possible signs of angioedema)

If you get any of these side effects, tell your doctor immediately.

Some side effects may be serious, but the frequency of these side effects is not known

(frequency cannot be estimated from the available data)

- Difficulty breathing with wheezing or coughing (signs of paradoxical bronchospasm)

Some side effects are common

(may affect up to 1 in 10 people)

- Dry mouth
- Difficulty sleeping

- Runny or stuffy nose, sneezing, sore throat
- Diarrhoea or stomach ache
- Musculoskeletal pain

Some side effects are uncommon

(may affect up to 1 in 100 people)

- Difficulty and pain when passing urine
- Painful and frequent urination
- Palpitations
- Rash
- Numbness
- Cough with sputum
- Dental caries
- Feeling of pressure or pain in the cheeks and forehead
- Nose bleeds
- Pain in arms or legs
- Pain in muscles, bones or joints of the chest
- Stomach discomfort after meals
- Throat irritation
- Tiredness
- Weakness
- Itching
- Voice alteration (hoarseness)
- Nausea
- Vomiting

Some elderly patients above 75 years of age experienced headache (frequency common) and urinary tract infection (frequency common).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland:

HPRA Pharmacovigilance
Website: www.hpra.ie

Malta:

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Seebri Breezhaler

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after “EXP”.

The expiry date refers to the last day of that month.

Do not store above 25°C.

Store the capsules in the original blister in order to protect from moisture. Do not remove from the blister until immediately before use.

The inhaler in each pack should be disposed of after all capsules in that pack have been used.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Seebri Breezhaler contains

- The active substance is glycopyrronium bromide. Each capsule contains 63 micrograms of glycopyrronium bromide (equivalent to 50 micrograms glycopyrronium). The delivered dose (the dose that leaves the mouthpiece of the inhaler) is equivalent to 44 micrograms of glycopyrronium.
- The other ingredients of the inhalation powder are lactose monohydrate and magnesium stearate.

What Seebri Breezhaler looks like and contents of the pack

Seebri Breezhaler 44 micrograms inhalation powder, hard capsules are transparent and orange and contain a white powder. They have the product code “GPL50” printed in black above and a company logo (ℓb) printed in black below a black bar.

Each pack contains a device called an inhaler, together with capsules in blisters. Each blister strip contains either 6 or 10 hard capsules.

The following pack sizes are available:

Packs containing 6x1, 10x1, 12x1 or 30x1 hard capsules, together with one inhaler.

Multipacks containing 90 (3 packs of 30x1) hard capsules and 3 inhalers.

Multipacks containing 96 (4 packs of 24x1) hard capsules and 4 inhalers.

Multipacks containing 150 (15 packs of 10x1) hard capsules and 15 inhalers.

Multipacks containing 150 (25 packs of 6x1) hard capsules and 25 inhalers.

Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Novartis Europharm Limited
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Elm Park, Merrion Road
Dublin 4
Ireland

Manufacturer

Novartis Farmacéutica SA
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Tel: +353 1 260 12 55

Malta

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Tel: +356 2122 2872

United Kingdom

Novartis Pharmaceuticals UK Ltd.
Tel: +44 1276 698370

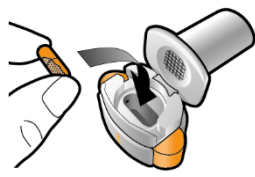
This leaflet was last revised in 01/2020

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website:
<http://www.ema.europa.eu>

Instructions for use of Seebri Breezhaler inhaler

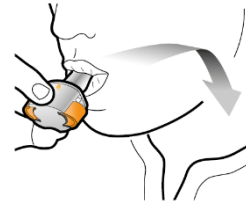
Please read the full **Instructions for Use** before using the Seebri Breezhaler.



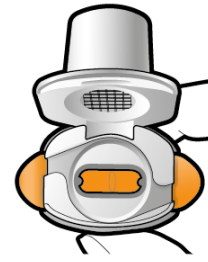
Insert



Pierce and release



Inhale deeply



Check capsule is empty

1

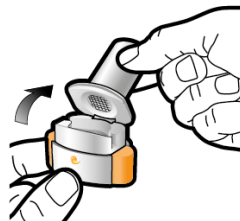
2

3

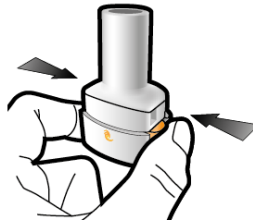
Check



Step 1a:
Pull off cap



Step 1b:
Open inhaler



Step 2a:
Pierce capsule once
Hold the inhaler upright. Pierce capsule by firmly pressing both side buttons at the same time. You should hear a noise as the capsule is pierced. Only pierce the capsule once.



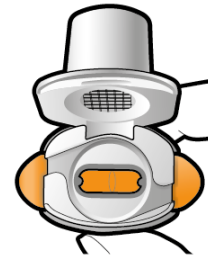
Step 2b:
Release side buttons



Step 3a:
Breathe out fully
Do not blow into the inhaler.




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. Do not press the side buttons.

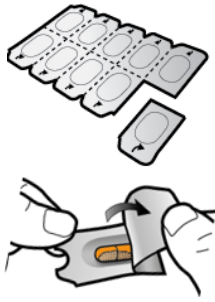


Check capsule is empty
Open the inhaler to see if any powder is left in the capsule.

If there is powder left in the capsule:
Close the inhaler.
Repeat steps 3a to 3c.


Powder remaining


Empty



Step 1c:

Remove capsule

Separate one of the blisters from the blister card.

Peel open the blister and remove the capsule.

Do not push the capsule through the foil.

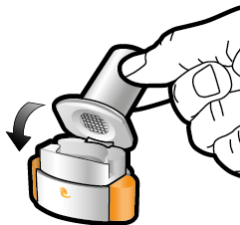
Do not swallow the capsule.



Step 1d:

Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:

Close inhaler

Breathe in quickly and as deeply as you can. During inhalation you will hear a whirring noise. You may taste the medicine as you inhale.



Step 3c:

Hold breath

Hold your breath for up to 5 seconds.



Remove empty capsule

Put the empty capsule in your household waste.

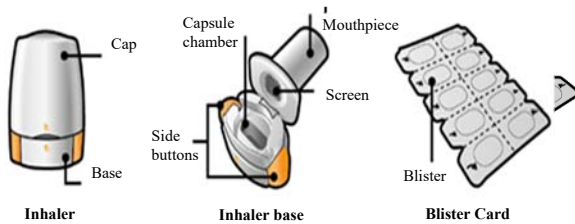
Close the inhaler and replace the cap.

Important Information

- **Seebri 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 **Seebri Breezhaler** capsules with any other inhaler.
- Do not use the **Seebri Breezhaler** inhaler to take any other capsule medicine.
- Never place the capsule into your mouth or the mouthpiece of the inhaler.
- Do not press the side buttons more than once.
- Do not blow into the 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.

Your Seebri Breezhaler Inhaler pack contains:

- One Seebri Breezhaler inhaler
- One or more blister cards, each containing either 6 or 10 Seebri Breezhaler capsules to be used in the inhaler



Frequently Asked Questions

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

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

I coughed after inhaling – does this matter?

This may happen. As long as the capsule is empty you have received enough of your 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 will be increased 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 your inhaler with water.

Disposing of the inhaler after use

Each inhaler should be disposed of after all capsules have been used. Ask your pharmacist how to dispose of medicines and inhalers that are no longer required.