

SEEBRI[®] BREEZHALER[®] Inhalation Powder Hard Capsules

Glycopyrronium bromide (50 microgram)

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What Seebri Breezhaler is used for

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

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).

How Seebri Breezhaler works

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 Seebri Breezhaler once a day, it will help to reduce the effects of COPD on your everyday life.

Before you use Seebri Breezhaler

When you must not use it

Do not use Seebri Breezhaler

If you are allergic to glycopyrronium bromide or any of the other ingredients of this

medicine (listed under Product Description)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think that 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.

Children and adolescents

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

Before you start to use it

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

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.

Taking other medicines

Tell your doctor or a 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 (also 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).

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 take 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 long to use 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 take Seebri Breezhaler, talk to your doctor or pharmacist.

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 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 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.

If you take more Seebri Breezhaler than you should (overdose)

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

While you are using it

Things you must do

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 tongue, lips and 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.

Things you must not do

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.

Things to be careful of

Driving and using machines

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

Side effects

Like all medicines, Seebri Breezhaler 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 (hyperglycemia; 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 have also experienced headache (frequency common) and urinary tract infection (frequency common).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Seebri Breezhaler

- Storage

- 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 30°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 show signs of tampering

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

In this pack, you will find a device called an inhaler together with capsules in blister strips.

The capsules are clear orange colored capsules containing a white powder. The capsules have a black product code "GPL50" printed above, and a black company logo (b) printed below a black line. Each capsule contains 50 microgram active substance.

Ingredients:

- Active ingredient(s)

The active substance is glycopyrronium bromide. Each capsule contains 50 micrograms glycopyrronium

- Inactive ingredients

The other ingredients of the inhalation powder are lactose monohydrate and magnesium stearate. The shell of the capsule contains hypromellose, purified water, carrageenan, potassium chloride and FDC Yellow 6 (110 Sunset Yellow FCF).

Pack size:

Each Seebri Breezhaler pack contains 30 capsules and 1 inhaler.

MAL number:

MAL14015011ACRZ

Manufacturer

Siegfried Barbera, S.L.,
Ronda de Santa Maria,
158 08210 Barbera del
Valles, Barcelona, Spain.

Product Registration Holder

Novartis Corporation (Malaysia)
Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor

Information Issued

11/02/2020, EU 28/01/2020

Date of Revision

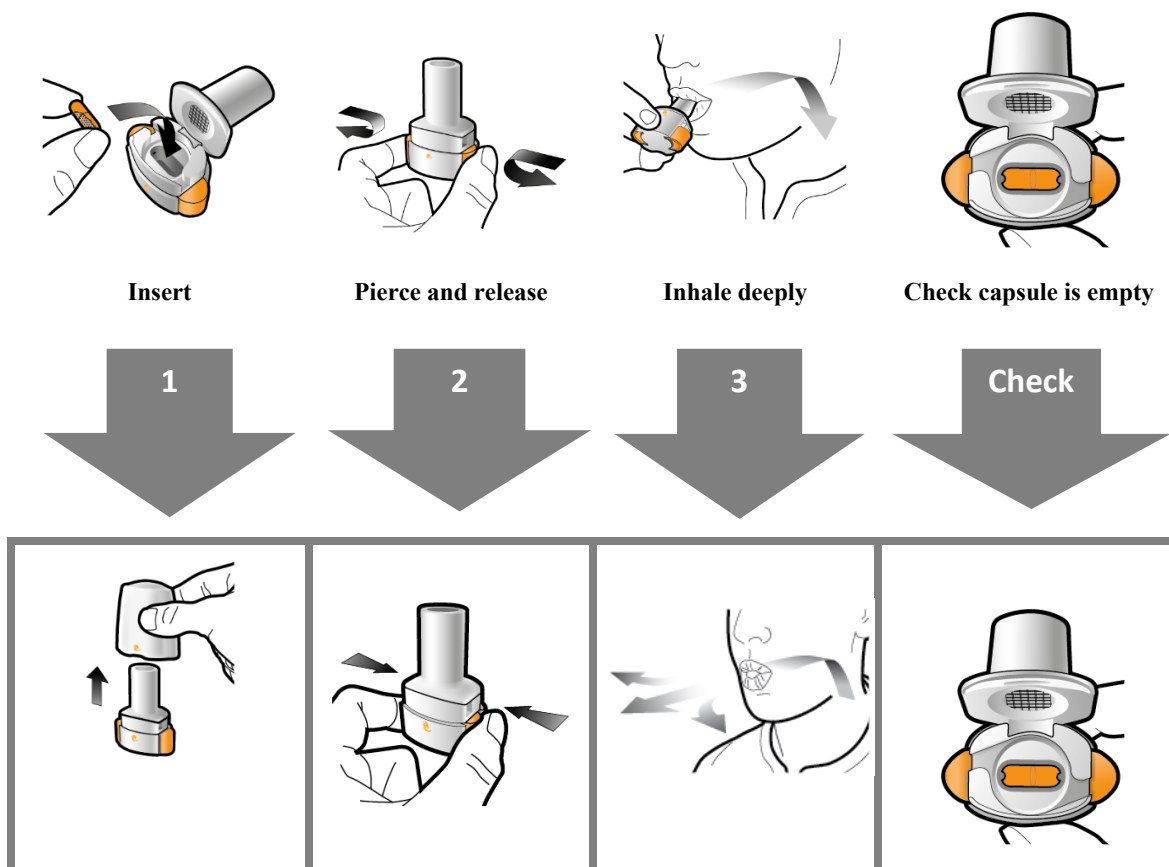
10/05/2022

Serial Number

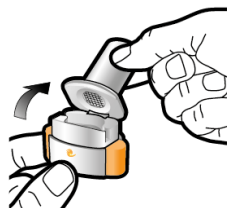
NPRA (R1/4) 21042022/098

Instructions for use of Seebri Breezhaler inhaler

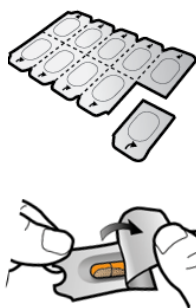
Please read the full **Instructions for Use** before using the Seebri Breezhaler.



Step 1a:

Pull off cap

Step 1b:

Open inhaler

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 2a:

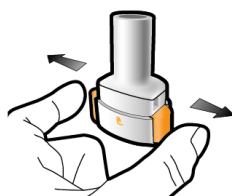
Pierce capsule once

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.



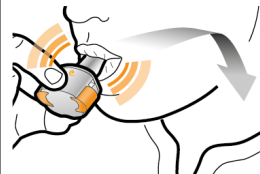
Step 2b:

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.

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.

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:

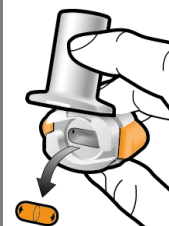
Close the inhaler.

Repeat steps 3a to 3c.



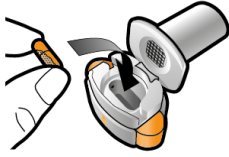
Powder
remaining

Empty

**Remove empty capsule**

Put the empty capsule in your household waste.

Close the inhaler and replace the cap.



Step 1d:

Insert capsule

Never place a capsule directly into the mouthpiece.



Step 1e:

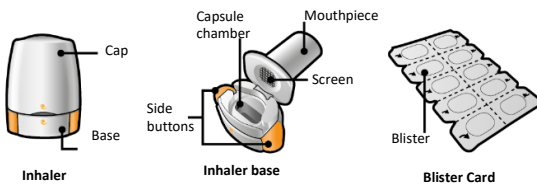
Close inhaler

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?

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.

	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.	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.
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