NOVARTIS

SEEBRI BREEZHALER®

(glycopyrronium bromide)

50 µg (Dry Powder Inhalation Capsules)

Patient Information Leaflet

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SCHEDULING STATUS: S3

PRODUCT NAME

SEEBRI BREEZHALER® Dry Powder Inhalation Capsules

The active ingredient in **SEEBRI BREEZHALER®** is Glycopyrronium bromide (glycopyrrolate)

Read all of this leaflet carefully before using SEEBRI BREEZHALER®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care providers.
- **SEEBRI BREEZHALER®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 is its used for

The active ingredient of **SEEBRI BREEZHALER** is micronised glycopyrronium bromide (glycopyrrolate) powder equivalent to 50 μg glycopyrronium.

2. What you need to know before you use SEEBRI BREEZHALER®

SEEBRI BREEZHALER is used to make breathing easier for people who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD).

Do not use SEEBRI BREEZHALER

- If you are allergic to glycopyrronium, lactose or any of the other ingredients of SEEBRI BREEZHALER, listed in section 6.
- If you have severe kidney problems

Take special care with SEEBRI BREEZHALER

Before using SEEBRI BREEZHALER, tell your doctor 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 SEEBRI BREEZHALER and tell your doctor immediately** if you experience tightness of the chest, coughing, wheezing or breathlessness directly after using SEEBRI BREEZHALER (signs of bronchospasm)
- **stop taking SEEBRI BREEZHALER and tell your doctor immediately** if you experience difficulties in breathing or swallowing, swelling of tongue, lips and face, skin rash, itching and hives (signs of allergic reaction).
- **stop taking SEEBRI BREEZHALER and tell your doctor immediately** 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 SEEBRI BREEZHALER to treat a sudden attack of breathlessness or wheezing.

Using SEEBRI BREEZHALER with food and drink

You can inhale SEEBRI BREEZHALER any time before or after food or drink.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using your SEEBRI BREEZHALER.

Driving and using machines

Treatment with SEEBRI BREEZHALER may lead to tiredness, dizziness or spinning sensation. You should therefore be cautious when driving or using machines during your treatment with SEEBRI BREEZHALER.

Important information about some of the ingredients of SEEBRI BREEZHALER

SEEBRI BREEZHALER contains lactose (milk sugar). If you have severe lactose intolerance, tell your doctor before taking SEEBRI BREEZHALER**.**

Using other medicines with SEEBRI BREEZHALER

Always tell your healthcare professional if you are taking any other medicine, including complementary and traditional medicines.

This includes medicines similar to SEEBRI BREEZHALER used for your lung disease. It is not recommended to use SEEBRI BREEZHALER with anticholinergics such as ipratropium, oxitropium or tiotropium.

No specific side effects have been reported when SEEBRI BREEZHALER has been taken together with other products used to treat COPD such as relievers inhalers, e.g. salbutamol, methylxanthines, e.g. theophylline and/or oral and inhaled steroids e.g. prednisolone.

3. How to use SEEBRI BREEZHALER

Do not share medicines prescribed for you with any other person.

Always use SEEBRI BREEZHALER exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

How much SEEBRI BREEZHALER to inhale

The usual dose is to inhale the content of one capsule each day. Do not use more than your doctor tells you to use.

When to inhale SEEBRI BREEZHALER

You only need to inhale once a day to help you breathe easier because SEEBRI BREEZHALER lasts for 24 hours.

Using SEEBRI BREEZHALER at the same time each day will also help you to remember to use it.

How to use the SEEBRI BREEZHALER

In this pack, you will find an inhaler and capsules (in blister strips) that contain the medicine as inhalation powder.

Only use the inhaler contained in this pack (SEEBRI BREEZHALER inhaler) to inhale the powder in a capsule.

Do not swallow the capsules.

Capsules should always be stored in the blister strip and only removed immediately before use.

When you start a new pack, use the new SEEBRI BREEZHALER inhaler supplied in this new pack.

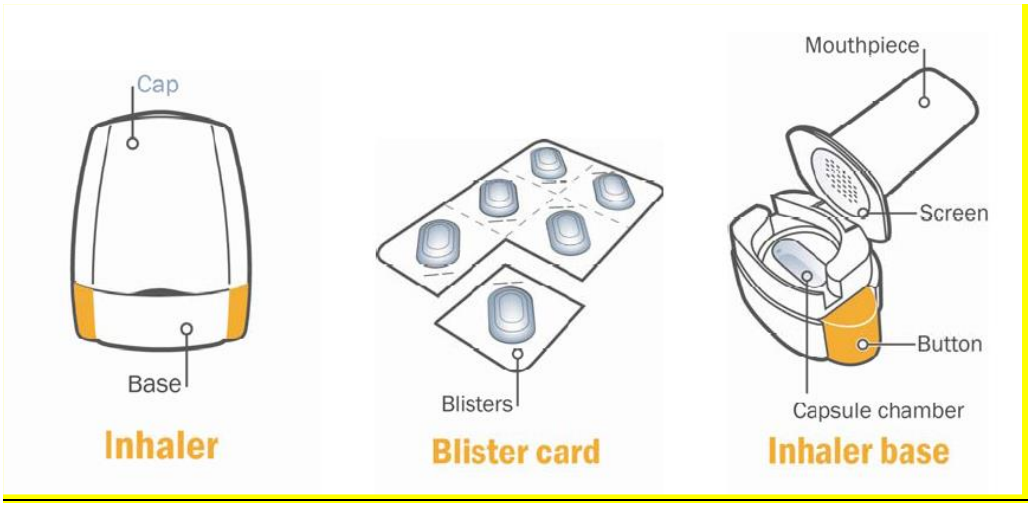
Dispose of each inhaler after 30 days of use.

Ensure reading the instructions on how to use the SEEBRI BREEZHALER inhaler provided below.

Your SEEBRI BREEZHALER pack

One SEEBRI BREEZHALER pack contains:

- one SEEBRI BREEZHALER inhaler
- one or more blisters containing SEEBRI BREEZHALER capsules to be used in the inhaler



Only use the SEEBRI BREEZHALER inhaler contained in this pack. Do not use SEEBRI BREEZHALER capsules with any other inhaler, do not use SEEBRI

BREEZHALER inhaler to take any other capsule medicine.

Dispose each inhaler after 30 days of use. Ask your pharmacist how to dispose of medicines and inhalers no longer required.

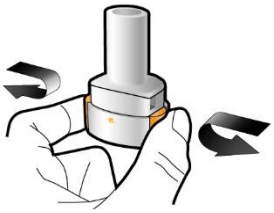
Do not swallow SEEBRI BREEZHALER capsules. The powder in the capsules is for you to inhale.

How to use your inhaler

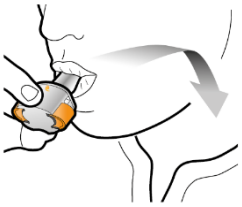
Please read the full **Instructions for Use** before using the **SEEBRI BREEZHALER®**.



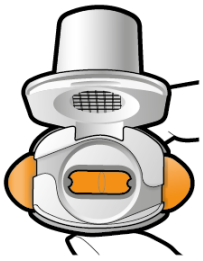
Insert



Pierce and release

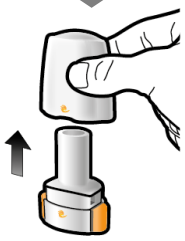


Inhale deeply

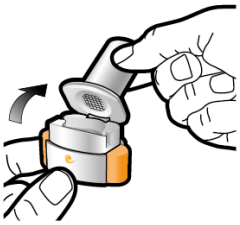


Check capsule is empty

1

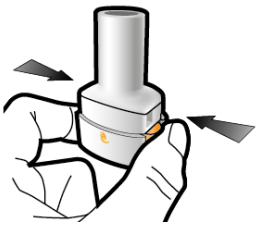


Step 1a:
Pull off cap

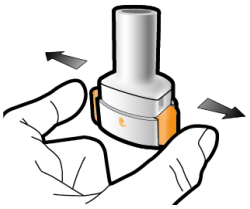


Step 1b:
Open inhaler

2



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.

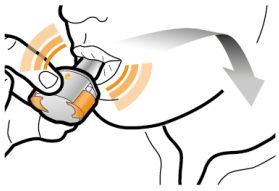


Step 2b:
Release side buttons

3

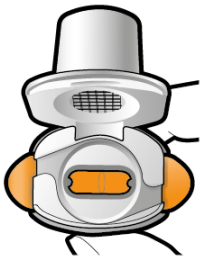


Step 3a:
Breathe out fully
Do not blow into the inhaler.



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.
<u>Do not press the side buttons</u>.

Check



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

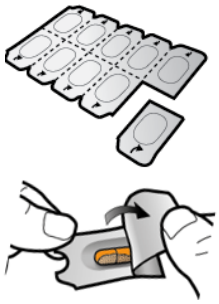
If there is powder left in the capsule:
Close the inhaler.
Repeat steps 3a to 3c.



Powder remaining



Empty

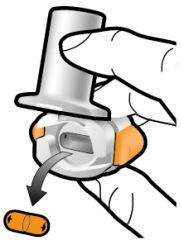


Step 1c:
Remove capsule
Separate one of the blisters from the blister card.
Peel open the blister and remove the capsule.
Do not push the capsule through the foil.
Do not swallow the capsule.

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.



Step 1d:
Insert capsule
Never place a capsule directly into the mouthpiece.



Step 1e:
Close inhaler

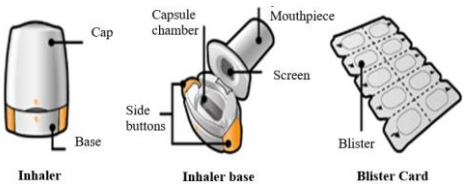
Important Information

- **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?
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.

REMEMBER:

- **Do not swallow SEEBRI BREEZHALER capsules.**

- **Only use the SEEBRI BREEZHALER inhaler contained in this pack.**

- SEEBRI BREEZHALER capsules must always be stored in the blister, and only removed immediately before use.

- Never place a SEEBRI BREEZHALER capsule directly into the mouthpiece of the SEEBRI BREEZHALER inhaler.

- Do not press the piercing buttons more than once.

- Never blow into the mouthpiece of the SEEBRI BREEZHALER inhaler.

- Always release the push buttons before inhalation.

- Never wash the SEEBRI BREEZHALER inhaler with water. Keep it dry. See below “How to clean your inhaler”.

- Never take the SEEBRI BREEZHALER inhaler apart.

- Always use the new SEEBRI BREEZHALER inhaler that comes with your new SEEBRI BREEZHALER medication pack.

- Do not store the capsules in the SEEBRI BREEZHALER inhaler.

- Always keep the SEEBRI BREEZHALER inhaler and SEEBRI BREEZHALER capsules in a dry place.

Additional information

Occasionally, very small pieces of the capsule can get past the screen and enter your mouth. If this happens, you may be able to feel these pieces on your tongue. It is not harmful if these pieces are swallowed or inhaled. The chances of the capsule shattering will be increased if the capsule is pierced more than once (step 7).

How to clean your inhaler

Never wash your inhaler with water. If you want to clean your inhaler wipe the mouthpiece inside and outside with a clean, dry lint-free cloth to remove any powder residue. Keep the inhaler dry.

How long to continue to take SEEBRI BREEZHALER

Keep using SEEBRI BREEZHALER for as long as your doctor tells you.

COPD is a long-term disease and you should use SEEBRI BREEZHALER 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.

If you use more SEEBRI BREEZHALER than you should

If you have inhaled too much SEEBRI BREEZHALER or if someone else accidentally uses your medicine, contact a doctor or hospital for advice immediately. Show the pack of SEEBRI BREEZHALER. Medical attention may be needed.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take SEEBRI BREEZHALER

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

4. Possible Side Effects

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SEEBRI BREEZHALER, please consult your doctor, pharmacist or other health care professional for advice.

Some side effects could be serious

These side effects are less frequent

- Irregular heart beat (possible signs of atrial fibrillation)
- High level of blood sugar (hyperglycemia; typical symptoms include excessive thirst or hunger and frequent urination)
- Swelling mainly of the tongue, lips, face and throat (possible signs of angioedema)

- Difficulty in breathing or swallowing, swelling of tongue, lips and face, skin rash, itching and hives (signs of allergic reactions).
- Difficulty breathing with wheezing or coughing (signs of paradoxical bronchospasm).

If you experience any of these, **tell your doctor immediately**

Patients using SEEBRI BREEZHALER may experience side effects

Some side effects are frequent

- Dry mouth
- Nausea, vomiting, diarrhoea and abdominal pain (possible symptoms of gastroenteritis)
- Difficulty sleeping
- Runny or stuffy nose, sneezing (rhinitis, sore throat)
- Musculoskeletal pain
- Neck pain

If any of these affects you severely, **tell your doctor.**

Some side effects are less frequent

- Stomach discomfort after meal (possible symptoms of dyspepsia)
- Dental caries
- Pain in extremities (e.g. arms or legs)
- Pain in muscles, bones or joints of the chest
- Rash
- Tiredness
- Weakness
- Feeling of pressure or pain in the cheeks and forehead (possible symptoms of sinus congestion)
- Cough with sputum
- Throat irritation
- Nose bleeds

- Painful and frequent urination (possible symptoms of cystitis)
- Difficulty and pain when passing urine (possible symptoms of dysuria)
- Palpitations
- Numbness
- Itching

If any of these affects you severely, **tell your doctor.**

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Some elderly patients above 75 years of age have also experienced headache and urinary tract infection.

If any of these affects you severely, **tell your doctor.**

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to patientsafety.sacg@novartis.com and via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA`s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store SEEBRI BREEZHALER

- Store at or below 25 °C and protect from moisture
- SEEBRI BREEZHALER capsules must always be stored in the blister to protect from moisture and only removed immediately before use.
- Do not store the medicine in the bathroom and or in the sun.
- **KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.**
- Do not use the capsules after the expiry date printed on the blister or label.
- Return all unused medicine to your pharmacist
- Each inhaler should be disposed of after 30 days of use.

- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

Aluminium foil blisters made of silver forming foil (polyamide /aluminium/polyvinyl chloride) sealed to a white backing foil (polyethylene terephthalate/aluminium).

Each blister strip containing 6 capsules per blister is enclosed in a cardboard carton with 1 inhaler device.

Pack sizes: 10,12, 30, 90 or 150 capsules with 1 inhaler.,

The other inactive ingredients of SEEBRI BREEZHALER are:

Lactose monohydrate (which contains milk proteins) and magnesium stearate. The capsule shell components: carrageenan, FDC Yellow 6 (110 Sunset Yellow FCF) hypromellose, potassium chloride

IDENTIFICATION OF SEEBRI BREEZHALER

Hard hypromellose capsule: Transparent orange cap and body. *Imprint - Cap*: black " " under radial black bar; *Body:* black "GPL 50" above black radial bar. Size: 3.

Powder: White to practically white powder is contained in the capsule.

HOLDER OF CERTIFICATE OF REGISTRATION:

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

2090

This leaflet was last revised in:

18 August 2020

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Namibia: 15/10.2/0154	NS1
Botswana: BOT1803318A	S2

Tracking Numbers:

2012-PSB/GLC-0563s, 2013-PSB/GLC-0660s, 2014-PSB/GLC-0726s, 2016-PSB/GLC-0810s