

SEEBRI® BREEZHALER®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SEEBRI BREEZHALER?

SEEBRI BREEZHALER contains the active ingredient glycopyrronium bromide (glycopyrrolate). SEEBRI BREEZHALER is used to treat chronic obstructive pulmonary disease (COPD). This is a serious lung condition caused by damage to the lungs.

For more information, see Section [1. Why am I using SEEBRI BREEZHALER?](#) in the full CMI.

2. What should I know before I use SEEBRI BREEZHALER?

Do not use if you have ever had an allergic reaction to SEEBRI BREEZHALER or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SEEBRI BREEZHALER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SEEBRI BREEZHALER and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SEEBRI BREEZHALER?

- Your doctor will advise you of the appropriate dose.
- Inhale the contents of one capsule once daily.

More instructions can be found in Section [4. How do I use SEEBRI BREEZHALER?](#) in the full CMI.

5. What should I know while using SEEBRI BREEZHALER?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using SEEBRI BREEZHALER.
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	<ul style="list-style-type: none"> • Use this medicine exactly as prescribed by your doctor or pharmacist. • Tell your doctor immediately if you experience difficulties in breathing.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not use this medicine to treat any other problems unless your doctor tells you to. • Do not swallow SEEBRI BREEZHALER capsules.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how SEEBRI BREEZHALER affects you.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • Do not store above 30°C. • The capsules must always be stored in the

	blister pack to protect from moisture and light.
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For more information, see Section [5. What should I know while using SEEBRI BREEZHALER?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include dry mouth, vomiting, diarrhoea, difficulty sleeping, fatigue, unusual weakness, headache, numbness, stomach discomfort, sinus congestion, chesty cough, sore throat, hoarse voice, pain in muscles, bones, joints, neck, arms or legs, rash, itching. Serious side effects include difficulty in breathing or swallowing, signs of an allergic reaction (swelling of tongue, lips and face, skin rash, itching and hives), difficulty breathing with wheezing or coughing, fast or irregular heartbeats, chest pain, swelling mainly of the tongue, lips, face and throat, excessive thirst or hunger and frequent urination, difficulty passing urine or painful urination.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SEEBRI® BREEZHALER®

Active ingredient: Glycopyrronium bromide
(glycopyrrolate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SEEBRI BREEZHALER. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SEEBRI BREEZHALER.**

Where to find information in this leaflet:

- [1. Why am I using SEEBRI BREEZHALER?](#)
- [2. What should I know before I use SEEBRI BREEZHALER?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SEEBRI BREEZHALER?](#)
- [5. What should I know while using SEEBRI BREEZHALER?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SEEBRI BREEZHALER?

SEEBRI BREEZHALER contains the active ingredient glycopyrronium bromide (glycopyrrolate). SEEBRI BREEZHALER belongs to a group of medicines called bronchodilators. They help to relax the muscles around your airways in the lungs and keep them open, making breathing easier.

SEEBRI BREEZHALER is used to treat chronic obstructive pulmonary disease (COPD). It is a serious lung condition caused due to damage to the lungs. The damage results in irritation and swelling inside the airways. This limits the airflow into and out of the lungs. COPD symptoms include shortness of breath, cough that brings up mucus, chest discomfort.

2. What should I know before I use SEEBRI BREEZHALER?

Warnings

Do not use SEEBRI BREEZHALER if:

- you are allergic to glycopyrronium bromide (glycopyrrolate), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Symptoms of allergic reactions include swelling of the tongue, lips, and face, difficulties in breathing or swallowing, hives or skin rash.

Check with your doctor if you:

- have any kidney problems
- suffer from an eye problem called narrow-angle glaucoma
- have difficulty passing urine
- have heart problems.

Do not use SEEBRI BREEZHALER in children under 18 years of age.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

SEEBRI BREEZHALER is not recommended for use during pregnancy.

Your doctor will advise you regarding the possible risks and benefits of using SEEBRI BREEZHALER during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is unknown whether the active ingredients in SEEBRI BREEZHALER pass into breast milk.

Your doctor will advise you regarding the possible risks and benefits of using SEEBRI BREEZHALER during breast feeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with SEEBRI BREEZHALER and affect how it works.

Do not take SEEBRI BREEZHALER with anticholinergic drugs such as ipratropium, oxitropium or tiotropium.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SEEBRI BREEZHALER.

4. How do I use SEEBRI BREEZHALER?

How much to use

- Your doctor will advise you of the appropriate dose.
- The dose for adults is inhaling the contents of one capsule once daily.

- Follow the instructions provided and use SEEBRI BREEZHALER until your doctor tells you to stop.
- **Do not to take more than one capsule in a day.**

When to use SEEBRI BREEZHALER

SEEBRI BREEZHALER should be used at about the same time each day.

How to use SEEBRI BREEZHALER

- Carefully read the instructions and follow the diagrams inside the carton that show you how to use the BREEZHALER properly.
- Use SEEBRI capsules only for oral inhalation using the BREEZHALER inhaler.
- **Do not swallow the SEEBRI BREEZHALER capsules.**
- Keep the capsules in the blister pack and only remove them before using.
- Peel the backing away from the blister pack to open it; do not push the capsule through the foil.
- **If you do not understand how to use the inhaler, ask your doctor or pharmacist for advice.**

If you forget to use SEEBRI BREEZHALER

SEEBRI BREEZHALER should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible and then go back to using it as you would normally do.

Do not take more than one dose in a day.

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

Do not take a double dose to make up for the dose you missed.

If you use too much SEEBRI BREEZHALER

If you think that you have used too much SEEBRI BREEZHALER, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SEEBRI BREEZHALER?

Things you should do

Call your doctor straight away if you:

- develop any allergic reaction to SEEBRI BREEZHALER

- are pregnant or intend to become pregnant.
- experience any contraction in the airways causing difficulty in breathing.
- have any difficulty passing urine or painful urination.
- 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.

Use this medicine exactly as prescribed by your doctor or pharmacist.

Remind any doctor, dentist or pharmacist you visit that you are using SEEBRI BREEZHALER.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not swallow SEEBRI BREEZHALER capsules.
- Do not take more than one dose in a day.
- Do not use this medicine to treat any other problems unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they seem to have same condition as you.
- Do not use SEEBRI BREEZHALER in children under 18 years of age.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SEEBRI BREEZHALER affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Follow the instructions provided in the user leaflet on how to properly clean and take care of your SEEBRI BREEZHALER
- Store below 30°C.
- Always store SEEBRI BREEZHALER capsules in the blister pack to protect from moisture.
- Remove the capsules only before use.
- Dispose of each BREEZHALER inhaler after 30 days of use.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Discard your SEEBRI BREEZHALER when you have no capsules left.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General problems:</p> <ul style="list-style-type: none">• Dry mouth• Vomiting• Diarrhoea• Difficulty sleeping• Fatigue• Unusual weakness• Headache• Numbness• Stomach discomfort <p>Respiratory Problems:</p> <ul style="list-style-type: none">• Sinus congestion (feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>throbbing ache, fever, stuffy nose and loss of the sense of smell)</p> <ul style="list-style-type: none"> • Chesty cough • Sore throat • Hoarse voice <p>Muscle problems:</p> <ul style="list-style-type: none"> • Pain in muscles, bones, joints • Neck pain • Pain in arms or legs <p>Skin problems:</p> <ul style="list-style-type: none"> • Rash • Itching 	

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • Difficulty in breathing or swallowing, swelling of tongue, lips and face, skin rash, itching and hives 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Difficulty breathing with wheezing or coughing <p>Heart problems:</p> <ul style="list-style-type: none"> • Fast or irregular heart beats • Chest pain <p>Other problems:</p> <ul style="list-style-type: none"> • Excessive thirst or hunger and frequent urination (symptoms of high blood sugar levels) • Difficulty passing urine or painful urination 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What SEEBRI BREEZHALER contains

Active ingredient (main ingredient)	Glycopyrronium bromide (glycopyrrolate)
Other ingredients (inactive ingredients)	Capsule fill: Lactose monohydrate and magnesium stearate. Capsule shell components: Hypromellose, purified water, carrageenan, potassium chloride, Sunset Yellow FCF Printing Ink: Shellac, absolute ethanol, isopropyl alcohol, propylene glycol, butan-1-ol, ammonium hydroxide, potassium hydroxide, purified water, iron oxide black

Potential allergens	Lactose monohydrate
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Do not take this medicine if you are allergic to any of these ingredients.

What SEEBRI BREEZHALER looks like

Glycopyrronium bromide (glycopyrrolate) 50 microgram capsules:

Clear orange coloured hard capsules with black imprints. The capsules are marked with "GPL 50" and a black company logo. The capsules come in foil packs containing 30 capsules in a cardboard carton. (AUST R 191517)

BREEZHALER:

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

Who distributes SEEBRI BREEZHALER

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

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