

SEEBRI® BREEZHALER®

capsules for inhalation

Glycopyrronium bromide (glycopyrrolate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Seebri Breezhaler.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Seebri Breezhaler against the benefits they expect it will have for you.

If you have any concerns about having this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Seebri Breezhaler is used for

Seebri capsules are for the treatment of chronic obstructive pulmonary

disease, also called COPD. COPD is a serious lung condition that can cause difficulty in breathing, and constant coughing. Symptoms of COPD include shortness of breath, cough, chest discomfort and coughing up phlegm.

Seebri capsules for inhalation belong to a group of medicines called bronchodilators. These medicines are used to keep the air passages in the lungs open and make breathing easier.

Seebri Breezhaler block tightening of these muscles in the lungs, making it easier for air to get in and out of the lungs.

Seebri capsules for inhalation contain the active ingredient, glycopyrronium bromide (glycopyrrolate) in a capsule form.

The capsules are for oral inhalation only. The powder from the capsule is inhaled (breathed into the lungs), using the Breezhaler® inhalation device provided with the medicine.

Ask your doctor if you have any questions about why Seebri Breezhaler has been prescribed for you.

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

It is not addictive.

Before you use Seebri Breezhaler

When you must not use it

Do not use Seebri Breezhaler if you have ever had an allergic reaction to glycopyrronium bromide (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If this applies to you, tell your doctor without using Seebri Breezhaler.

If you think you may be allergic, ask your doctor for advice.

Do not breast-feed while you are using this medicine.

It is not known if the active ingredient passes into the breast milk and could affect your baby.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to use it

Tell your doctor if you have any of the following medical conditions:

- you have kidney problems
- you have an eye problem called narrow-angle glaucoma

- you have difficulty passing urine

Your doctor may want to take special precautions if you have any of the above conditions.

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.

Tell your doctor if you are pregnant or intend to become pregnant.

Seebri is not recommended for use during pregnancy. If it is necessary for you to use this medicine during pregnancy, your doctor will discuss with you the benefits and risks involved.

There are a number of other medicines that work in the same way as Seebri and that are commonly prescribed. Some of these similar medicines that can be used to treat your lung disease include ipratropium, oxitropium or tiotropium (also called anticholinergics). Please speak to your doctor or pharmacist if you still have any of these medicines because it may not be intended that you will use them while you are taking Seebri.

Taking other medicines

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

Some medicines and Seebri may interfere with each other. This includes medicines similar to Seebri used for your lung disease. It's not recommended to use Seebri with anticholinergics such as ipratropium, oxitropium or tiotropium. You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/

her before you start using Seebri Breezhaler.

How to use Seebri Breezhaler

You may have been given a treatment plan by your doctor to help you manage your COPD and to know what to do when it worsens. Make sure that you understand this plan by talking to your doctor and pharmacist about it. In particular, do not stop other medications that are used to treat COPD even if you feel well. Only stop other prescribed medications on medical advice.

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label or in the carton, ask your doctor or pharmacist for help.

How much to use

The dose for adults is the inhalation (puff) of the content of one capsule each day, every day. There is no gain to be had from exceeding this dose. Take your puff at the same time each day to help minimise your symptoms throughout the day and night. It will also help you remember to use your medicine.

How to use the Breezhaler

Carefully read the instructions and follow the diagrams inside the carton that show you how to use the Breezhaler properly.

Make sure you understand how to use the device properly. If you are not sure, ask your doctor or pharmacist for help.

How long to use it

Continue to use this medicine for as long as your doctor tells you to.

If it helps your breathing problems, your doctor may want you to keep using it for a long time. This medicine helps to control your condition but it does not cure it. You will need to use other medications as well and this will be outlined in your COPD management plan.

If you still smoke, you should stop. If you have not taken advice about an exercise program, consider asking for it.

If you forget to use it

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

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

Do not use a double dose to make up for the one that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much Seebri. Do this even if there are no signs of discomfort or poisoning.

While you are using Seebri Breezhaler

Things you must do

Only use the inhalation device contained in this pack.

Use this medicine exactly as your doctor has prescribed. Try not to miss any doses and use it even if you feel well.

If you do not follow your doctor's instructions, you may not get relief from your breathing problems or you may have unwanted side effects.

If you find that the usual dose of Seebri Breezhaler is not giving as much relief as before, or does not last as long as usual, contact your doctor so that your condition can be checked.

This is important to ensure your COPD is controlled properly.

During treatment with SEEBRI BREEZHALER:

- TELL YOUR DOCTOR IMMEDIATELY if you experience signs and symptoms of prostatic hyperplasia or bladder-neck obstruction (e.g., difficulty passing urine, painful urination).
- 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 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.

If you become pregnant while using this medicine, tell your doctor.

Your doctor can discuss with you the risks of using it while you are pregnant.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Seebri Breezhaler.

Tell any other doctor, dentist or pharmacist who treats you that you are using this medicine.

Things you must not do

Do not exceed the recommended daily dose - it will not help you to do this. Instead, check your COPD management plan and seek medical attention. Do not swallow the capsules.

Do not take any other medicines for your breathing problems without checking with your doctor.

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not use the Breezhaler inhaler after 30 days of use.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Seebri affects you.

This medicine may cause dizziness in some people. Make sure you know how you react before you drive a car, operate machinery, or do anything else that could be dangerous. If you are dizzy, do not drive.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Seebri Breezhaler.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- Dry mouth

- Nausea, vomiting, diarrhoea and abdominal pain (possible symptoms of gastroenteritis)
- Difficulty sleeping
- 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)
- Cough with sputum
- Throat irritation
- Painful and frequent urination (possible symptoms of cystitis)
- Difficulty and pain when passing urine (possible symptoms of dysuria)
- Palpitations
- Nose bleeds
- Runny or stuffy nose, sneezing (rhinitis), sore throat
- Musculoskeletal pain
- Neck pain
- Numbness
- Itching
- Voice alteration (hoarseness)

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

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- Irregular heart beat (possible signs of atrial fibrillation)
- 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)
- High level of blood sugar (hyperglycemia; typical symptoms include excessive thirst or hunger and frequent urination)

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects may only be found when your doctor orders blood tests from time to time.

After using Seebri Breezhaler

Cleaning and storage

- Follow the instructions in the carton on how to properly clean and take care of your Seebri Breezhaler.
- Store it in a cool dry place away from moisture.
- Do not store the device or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.
- Dispose of each Breezhaler inhaler after 30 days of use.

Keep this medicine where children cannot see or reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist how to dispose of it properly.

Product description

What it 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.

Breezhaler

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

Ingredients

Active Ingredient

Each capsule contains 50 micrograms of glycopyrronium as glycopyrronium bromide (glycopyrrolate).

Other ingredients

Seebri capsules also contain lactose and magnesium stearate.

Sponsor

Seebri Breezhaler is supplied in Australia by:

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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