NOVARTIS

BEMRIST BREEZHALER

(indacaterol/ mometasone furoate)

150/80, 150/160 and 150/320 micrograms inhalation powder, hard capsules

Patient Information Leaflet

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SCHEDULING STATUS: S4

BEMRIST BREEZHALER 150/80 micrograms inhalation powder hard capsules

BEMRIST BREEZHALER 150/160 micrograms inhalation powder hard capsules

BEMRIST BREEZHALER 150/320 micrograms inhalation powder hard capsules

(Indacaterol and mometasone furoate)

Contains sugar: lactose (Each capsule contains 25 mg of lactose monohydrate)

Read all of this leaflet carefully before you start using BEMRIST 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 healthcare provider.**
- **BEMRIST 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 BEMRIST BREEZHALER is and what it is used for

2. What you need to know before you use BEMRIST BREEZHALER

3. How to use BEMRIST BREEZHALER

4. Possible side effects

5. How to store BEMRIST BREEZHALER

6. Contents of the pack and other information

1. What BEMRIST BREEZHALER is

BEMRIST BREEZHALER contains two active substances called indacaterol and mometasone furoate.

Indacaterol belongs to a group of medicines called bronchodilators. They relax the muscles of the small airways in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When they are taken regularly, it helps the small airways to remain open.

Mometasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Corticosteroids reduce inflammation. They reduce the swelling and irritation in the small airways in the lungs and so gradually ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

In this pack, you will find an inhaler and capsules in blister cards that contain the medicine as inhalation powder. The inhaler enables you to inhale the medicine contained in a capsule. Only use the inhaler contained in this pack.

What BEMRIST BREEZHALER is used for

Your doctor has prescribed this medicine to treat asthma in adults and adolescents 12 years of age and older.

Asthma is a long-term lung disease where the muscles surrounding the smaller airways become tight (bronchoconstriction), swollen and irritated (inflammation). Symptoms come and go, and include shortness of breath, wheezing, chest tightness and cough.

You should use BEMRIST BREEZHALER every day as directed by your doctor and not only when you have breathing problems or other symptoms of asthma. This will make sure that it

works properly in controlling your asthma. It should not be used to relieve a sudden attack of breathlessness or wheezing.

If you have any questions about how BEMRIST BREEZHALER works or why it has been prescribed for you, ask your doctor.

2. What you need to know before you use BEMRIST BREEZHALER

Follow all of your doctor's instructions carefully.

Do not use BEMRIST BREEZHALER

- If you are allergic to indacaterol, mometasone furoate or other ingredients of this medicine (listed in section 6).
- If you think you may be allergic, ask your doctor for advice

Warnings and precautions

Before using BEMRIST BREEZHALER**,** tell your doctor or pharmacist if any of these apply to you:

- If you have heart problems, including an irregular or fast heartbeat.
- If you have thyroid gland problems.
- If you have ever been told that you have diabetes or high blood sugar.
- If you suffer from seizures or fits.
- If you have low potassium in your blood.
- If you have severe liver problems.
- If you have had tuberculosis (TB) of the lung, or have any long standing or untreated infections.

During treatment with BEMRIST BREEZHALER**:**

- **Stop taking BEMRIST BREEZHALER and seek medical help immediately** if you experience any of the following:
- Tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation of BEMRIST BREEZHALER (signs of paradoxical bronchospasm).
- Difficulty breathing or swallowing, swelling of the tongue, lips or face, skin rash, itching and hives (signs of allergic reaction)

Children and adolescents

You should not use BEMRIST BREEZHALER if you are under 12 years of age.

Older people (65 years or above)

You can use BEMRIST BREEZHALER at the same dose as for other adults if you are 65 years or older.

Other medicines and BEMRIST BREEZHALER

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) This includes in particular the following medicines:

- Medicines used in the treatment of depression (e.g. tricyclic antidepressants, monoamine oxidase inhibitors).
- Any medicines that may be similar to BEMRIST BREEZHALER (contain similar active substances); the use of these may increase the risk of experiencing possible side effects.

- Medicines that decrease the level of potassium in your blood. These include diuretics (also known as “water tablets” and used to treat high blood pressure, e.g. hydrochlorothiazide), other bronchodilators such as methylxanthines used for breathing problems (e.g. theophylline) or steroids (e.g. prednisolone).
- Medicine used to treat high blood pressure or other heart problems (e.g. propranolol) or to treat glaucoma (e.g. timolol).
- Medicine used to treat fungal infections (e.g., ketoconazole or itraconazole).
- Medicine used to treat HIV infection (e.g., ritonavir, nelfinavir or cobicistat).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Your doctor will discuss with you the potential risk of taking BEMRIST BREEZHALER during pregnancy or breast-feeding.

Mothers using BEMRIST BREEZHALER are advised to not breastfeed their babies.

Driving and using machines

If you experience headaches or neck pain after treatment with BEMRIST BREEZHALER, do not drive or use machines until you have confirmed that BEMRIST BREEZHALER does not affect your performance.

BEMRIST BREEZHALER contains:

- Capsule fill: Lactose (as monohydrate).
- Capsule shell components: Gelatin

Important information about some ingredient of BEMRIST BREEZHALER:

BEMRIST BREEZHALER contains lactose (milk sugar). Patients with the rare hereditary condition of lactose intolerance should not use BEMRIST BREEZHALER.

BEMRIST BREEZHALER contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to use BEMRIST BREEZHALER

Do not share medicines prescribed for you with any other person

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

Do not swallow the capsules, they are not meant for oral use.

How much BEMRIST BREEZHALER to inhale

There are three dose strengths of BEMRIST BREEZHALER, 150/80 micrograms, 150/160 micrograms and 150/320 micrograms. Your doctor will decide which dose strength is appropriate for you.

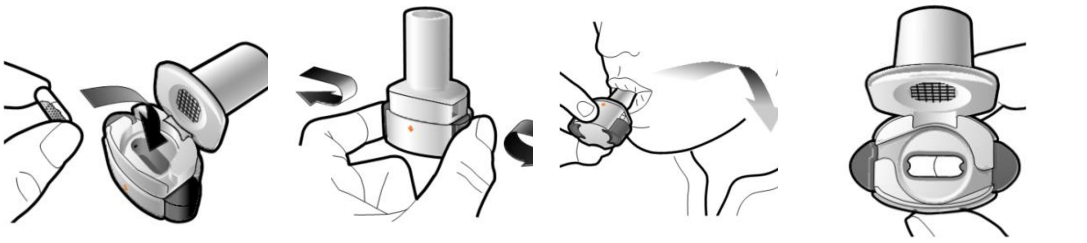
The usual dose is to inhale the content of one capsule each day. You only need to use this medicine once a day because its effect lasts for 24 hours. Do not use more than your doctor tells you to use.

You should inhale the content of one capsule of BEMRIST BREEZHALER every day and continue to use it even when you are not experiencing asthma symptoms.

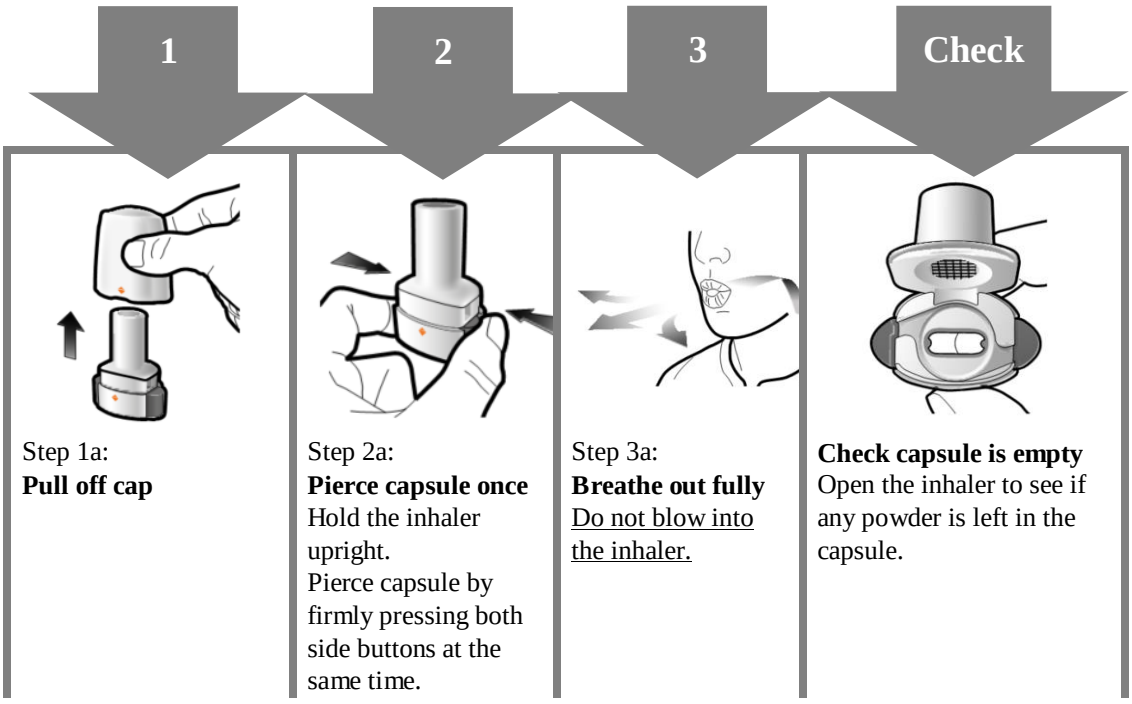
When to inhale BEMRIST BREEZHALER

Inhale BEMRIST BREEZHALER at the same time each day. This will help minimize your symptoms throughout the day and night. It will also help you remember to use your medicine.

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

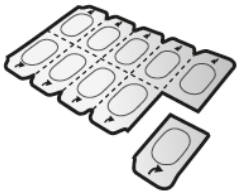


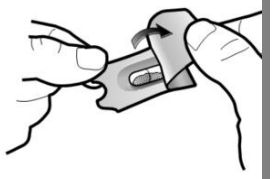
Insert **Pierce and release** **Inhale deeply** **Check capsule is empty**





Step 1b:
Open inhaler





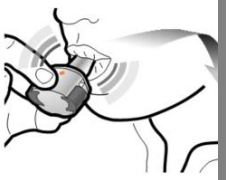
Step 1c:
Remove capsule
Separate one of the blisters from the blister card.

Peel open the blister and remove the capsule.
Do not push the capsule through the foil.
Do not swallow the capsule.

You should hear a noise as the capsule is pierced.
Only pierce the capsule once.



Step 2b:
Release side buttons



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.

Step 3d :
Rinse mouth
Rinse your mouth with water after

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



Powder remaining **Empty**



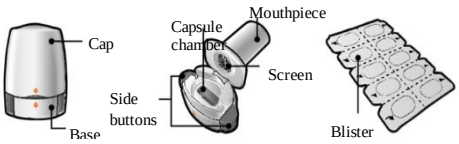
Remove empty capsule
Put the empty capsule in your household waste.

Close the inhaler and replace the cap.

 Step 1d: **Insert capsule** Never place a capsule directly into the mouthpiece.  Step 1e: **Close inhaler**		each dose and spit it out.	**Important Information** • BEMRIST 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 BEMRIST BREEZHALER capsules with any other inhaler. • Do not use the BEMRIST 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 BEMRIST BREEZHALER Inhaler pack contains:

- One BEMRIST BREEZHALER inhaler
- One or more blister cards each containing either 6 or 10 BEMRIST BREEZHALER capsules to be used in the inhaler



Inhaler **Inhaler base** **Blister card**

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 3d.

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 3d.

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.

How long to use BEMRIST BREEZHALER

Keep using BEMRIST BREEZHALER for as long as your doctor tells you. Don't stop unless your doctor advises you to, even if you feel better, as your symptoms may get worse.

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

If you use more BEMRIST BREEZHALER than you should

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

If you forget to use BEMRIST BREEZHALER

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

If you stop using BEMRIST BREEZHALER

Your asthma symptoms may come back if you stop using this medicine. If your asthma is not getting better or getting worse after you have started using BEMRIST BREEZHALER, talk to your doctor.

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

4. Possible side effects

BEMRIST BREEZHALER can have side effects.

Not all side effects reported for BEMRIST BREEZHALER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BEMRIST BREEZHALER, please consult your health care provider for advice.

Stop using BEMRIST BREEZHALER and seek medical help immediately if you experience any of the following:

- Difficulty breathing or swallowing, swelling of the tongue, lips, or face, skin rash, itching and hives (signs of allergic reaction and angioedema).

If you experience any serious side effects, stop taking this medicine and tell your doctor immediately.

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Frequent

- voice alteration (hoarseness)
- headache
- pain in muscles, bones or joints (signs of musculoskeletal pain)
- sore throat

Less frequent

- fast heart beat
- oral thrush (signs of candidiasis)
- high level of sugar in the blood
- muscle spasm
- skin itching
- rash

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA 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 BEMRIST BREEZHALER.

5. How to store BEMRIST BREEZHALER

- Store at or below 25°C.
- Protect from moisture and light.
- Store all medicines out of reach of children
- Do not use after the expiry date shown on the box.
- Store the capsules in the original blister, in a dry place in order to protect from moisture and light, and do not remove until immediately before use.
- Ask your pharmacist how to dispose of medicines you no longer use

6. Contents of the pack and other information

What BEMRIST BREEZHALER contains

Each capsule of BEMRIST BREEZHALER 150/80 micrograms, contains 173 micrograms of indacaterol acetate equivalent to 150 micrograms of indacaterol and 80 micrograms of mometasone furoate.

Each capsule of BEMRIST BREEZHALER 150/160 micrograms, contains 173 micrograms of indacaterol acetate equivalent to 150 micrograms of indacaterol and 160 micrograms of mometasone furoate.

Each capsule of BEMRIST BREEZHALER 150/320 micrograms, contains 173 micrograms of indacaterol acetate equivalent to 150 micrograms of indacaterol and 320 micrograms of mometasone furoate.

The other ingredients are

- Capsule fill: lactose (as monohydrate).
- Capsule shell: gelatin

What BEMRIST BREEZHALER looks like and contents of the pack

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

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

The inhaler device is a plastic device comprising white cap and white body with yellow translucent push buttons.

Pack sizes: 6, 12, 30, 90, 96 or 150 capsules.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

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BEMRIST BREEZHALER 150/160: 54/10.2.1/0871.868

BEMRIST BREEZHALER 150/320: 54/10.2.1/0872.869