

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BREZTRI AEROSPHERE 160/7,2/5,0 micrograms, pressurised inhalation, suspension

budesonide/glycopyrronium/formoterol fumarate dihydrate

Sugar free

Read all of this leaflet carefully before you start using BREZTRI AEROSPHERE:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BREZTRI AEROSPHERE 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 BREZTRI AEROSPHERE is and what it is used for
2. What you need to know before you use BREZTRI AEROSPHERE
3. How to use BREZTRI AEROSPHERE
4. Possible side effects
5. How to store BREZTRI AEROSPHERE
6. Contents of the pack and other information

1. What BREZTRI AEROSPHERE is and what it is used for

BREZTRI AEROSPHERE is an inhaler that is used for adult patients who have a lung disease called chronic obstructive pulmonary disease (COPD). BREZTRI AEROSPHERE is used to make breathing easier and help prevent worsening of COPD symptoms (exacerbations). COPD is a long-term disease of the airways in the lungs. In COPD, the muscles around the airways tighten which makes breathing difficult.

BREZTRI AEROSPHERE contains three active substances called budesonide, glycopyrronium and formoterol dihydrate.

- Budesonide belongs to a group of medicines called corticosteroids, and works by reducing and preventing inflammation in your lungs.

- Glycopyrronium and formoterol fumarate dihydrate belong to a group of medicines called bronchodilators, and work by blocking the tightening of the muscles in the lungs, making it easier for air to get in and out of the lungs.

BREZTRI AEROSPHERE delivers the active ingredients directly into your lungs as you breathe in. If you use this medicine twice a day, it will help to reduce the effects of COPD on your everyday life.

BREZTRI AEROSPHERE comes as a canister with an attached plastic collar and dose indicator, supplied with a yellow plastic actuator body and white mouthpiece. The mouthpiece is covered with a removable grey protective cap.

BREZTRI AEROSPHERE is supplied in a foil pouch that contains a drying packet (desiccant) and packed into a carton.

Each device contains 120 puffs.

2. What you need to know before you use BREZTRI AEROSPHERE

Do not use BREZTRI AEROSPHERE

- If you are hypersensitive (allergic) to budesonide, glycopyrronium, formoterol fumarate dihydrate or any of the other ingredients of BREZTRI AEROSPHERE.

Warnings and precautions

Special care should be taken with BREZTRI AEROSPHERE.

BREZTRI AEROSPHERE is a long-term maintenance treatment of COPD. Do not use this medicine to treat a sudden attack of breathlessness or wheezing.

Immediate breathing difficulties

If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your BREZTRI AEROSPHERE:

Stop using this medicine and seek medical help immediately, as you may have a serious condition called paradoxical bronchospasm.

Talk to your doctor before using BREZTRI AEROSPHERE:

- if you have high blood pressure or heart problems
- if you have diabetes

- if you have a lung infection
- if you have problems with your thyroid gland
- if you have low levels of potassium in your blood
- if you have prostate problems, or any problems passing urine
- if you have an eye problem called narrow-angle glaucoma
- if you have kidney or liver problems

Children and adolescents

BREZTRI AEROSPHERE is not for use in children or adolescents below 18 years of age.

Other medicines and BREZTRI AEROSPHERE

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

Some medicines may affect how this medicine works, or make it more likely that you'll have side effects.

These include:

- medicines called beta-blockers (such as atenolol or propranolol), to treat high blood pressure or other heart problems, or to treat glaucoma (such as timolol),
- ketoconazole or itraconazole, to treat fungal infections
- ritonavir or cobicistat, to treat HIV infection
- medicines that lower the amount of potassium in your blood, such as some diuretics (water tablets)
- other long-acting medicines similar to this medicine that are used to treat breathing problems, e.g. medicines containing tiotropium, ipratropium, aclidinium, umecclidinium or salmeterol, arformeterol, vilanterol, olodaterol or indacaterol. Don't use BREZTRI AEROSPHERE if you already use these medicines.
- medicines which are used to treat heart rhythm problems, e.g. amiodarone

Ask your doctor or pharmacist if you are not sure. The use of BREZTRI AEROSPHERE with these medicines is not recommended.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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

Driving and using machines

It is unlikely that BREZTRI AEROSPHERE will affect your ability to drive and use machines.

3. How to use BREZTRI AEROSPHERE

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

Use BREZTRI AEROSPHERE exactly as described in this leaflet or as your doctor have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is two inhalations taken twice daily.

Remember: Always rinse your mouth out with water after morning and evening doses. Do not swallow.

It is important to use BREZTRI AEROSPHERE every day, even if you have no COPD symptoms at the time.

- Instructions for use: Refer to Instructions for Use at the end of this leaflet. If you are not sure of how to use BREZTRI AEROSPHERE, contact your doctor or pharmacist.

Using BREZTRI AEROSPHERE with a spacer:

If you find it difficult breathing in and pressing the inhaler at the same time talk to your doctor or pharmacist. You may be able to use a spacer with your inhaler.

If you use more BREZTRI AEROSPHERE than you should

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

Signs of overdosage are blurred vision, dry mouth, nausea, muscle spasm, tremor, headache, increased heart rate and increased blood pressure.

If you forget to use BREZTRI AEROSPHERE

Do not take a double dose to make up for a forgotten dose. Take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not take more than two puffs twice a day.

If you stop using BREZTRI AEROSPHERE

This medicine is for long-term use. If you want to stop treatment, first talk to your doctor, as your symptoms may worsen.

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

4. Possible side effects

BREZTRI AEROSPHERE can have side effects.

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

Common side effects: may affect up to 1 in 10 people

- thrush (a fungal infection) in the mouth
- high blood sugar levels
- feeling anxious
- difficulty sleeping
- headache
- feeling sick (nausea)
- painful and frequent urination (may be signs of a urinary tract infection)
- coughing and/or a hoarse voice
- muscle cramps
- palpitations (awareness of your heart beating)
- pneumonia (infection of the lung)

Tell your doctor if you have any of the following while taking BREZTRI AEROSPHERE, they could be symptoms of a lung infection:

- fever or chills,
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

Uncommon side effects: may affect up to 1 in 100 people

- shaking/tremor
- dry mouth
- mild irritation in the throat
- bruising of the skin
- feeling restless, nervous or agitated
- depression
- fast heart beat or irregular heart beat
- chest pain or tightening in the chest (angina pectoris)
- feeling dizzy
- difficulty passing urine
- bronchospasm (tightening of the muscles in the airways which causes wheezing and trouble breathing).
- hypersensitivity

Very rare: may affect up to 1 in 10 000 people

- changes in behaviour
- reduced function of the adrenal gland

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BREZTRI AEROSPHERE.

5. How to store BREZTRI AEROSPHERE

Store all medicines out of reach of children.

Store at or below 30 °C. Store in a dry place.

Use by date: Do not use BREZTRI AEROSPHERE after the expiry date on the label/carton. The expiry date refers to the last date of the month.

To be used within 3 months of opening the pouch.

Return all unused medicine to your pharmacist.

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

Warning: The canister should not be broken, punctured or burnt, even when it seems empty. Do not use or store near heat or open flames. Do not expose to temperatures higher than 50 °C.

6. Contents of the pack and other information

What BREZTRI AEROSPHERE contains

- The active substances are budesonide, glycopyrronium and formoterol fumarate dihydrate
- The other ingredients are hydrofluoroalkane (HFA-134a), 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), calcium chloride.

What BREZTRI AEROSPHERE looks like and contents of the pack

BREZTRI AEROSPHERE is a pressurised inhalation, suspension.

BREZTRI AEROSPHERE comes as a canister with a dose indicator, supplied with a yellow plastic actuator body and white mouthpiece. The mouth piece is covered with a removable grey protective cap.

BREZTRI AEROSPHERE is supplied in a foil pouch that contains a drying packing (desiccant) and packed into a carton.

Pack size of 1 container of 120 actuations.

Holder of Certificate of Registration

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Registration number

59/10.3/0375

Read prior to using inhaler

INSTRUCTIONS FOR USE

BREZTRI AEROSPHERE

(budesonide, glycopyrronium and formoterol fumarate dihydrate)

Pressurised inhalation, suspension

For oral inhalation use

Please read these instructions carefully

Your BREZTRI AEROSPHERE (called “inhaler” in this leaflet) may be different from inhalers you have used before.

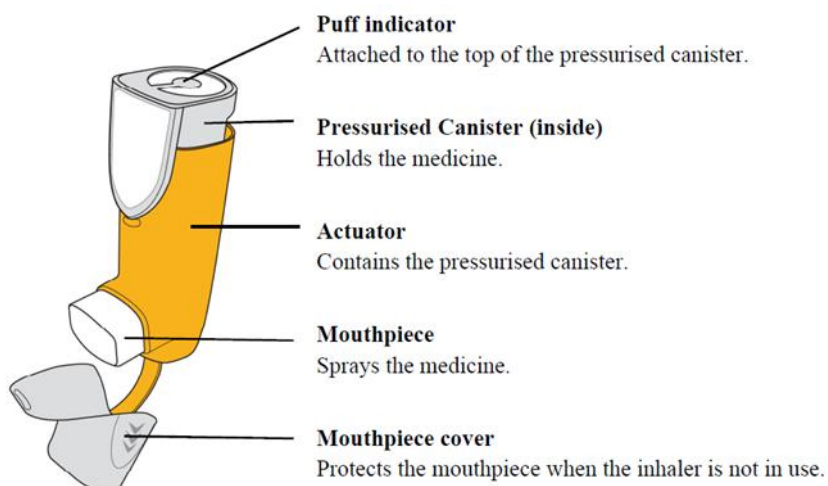
Important information

- **For oral inhalation use only**
- **Prepare your inhaler for its first time use by priming it**
- **Rinse your yellow actuator weekly**
- **Take 2 puffs of medicine in the morning and 2 puffs of medicine in the evening**

Storing your inhaler

- Store your inhaler at room temperature at or below 30 °C
- **Do not store in a humid environment, such as a bathroom**
- Keep your inhaler and all medicines out of the reach of children

Parts of your inhaler



Reading the puff indicator

The puff indicator will count down by 1 each time you spray a puff of a medicine

Pointer

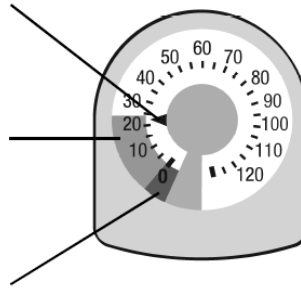
Points to number of puffs remaining

Yellow zone

Order a new inhaler when the pointer is in the yellow zone

Red zone

Throw away your inhaler when the pointer is at 0 in the red zone



Do not try to take a puff when the pointer is at 0 because you will not receive a full dose.

Ordering a new inhaler

- Order a new inhaler when the pointer on the puff indicator is in the yellow zone.

Throwing away your inhaler

Throw away your inhaler following local guidelines when:

- puff indicator show 0
- or
- **3 months** after your inhaler has been removed from the foil pouch

Do not reuse or use the actuator with medicine canisters from other inhalers.

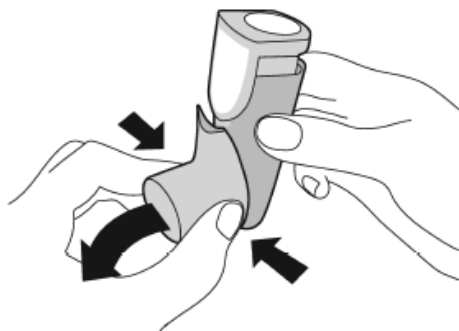
Do not puncture or throw the canister into a fire or incinerator.

BEFORE FIRST USE – Prime your inhaler 4 times before first use

Before you use your inhaler for the first time, prime it so that you will get the right amount of medicine when you use it.

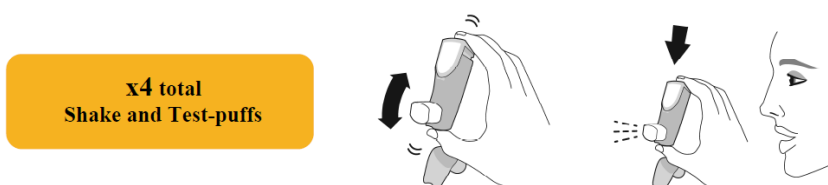
Prime 1

Remove mouthpiece cover.



Prime 2

Shake the inhaler well and spray **1 Test-puff** into the air facing away from you. Repeat for a total of **4 Test-puffs**, shaking before each Test-puff.

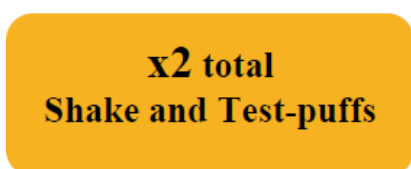


Extra puffs are provided for priming. **Do not skip priming.**

Re-prime your inhaler:

- after rinsing the actuator
- if dropped
- if not used for more than 7 days

To reprime, spray **2 Test-puffs**, shaking before each Test-puff.

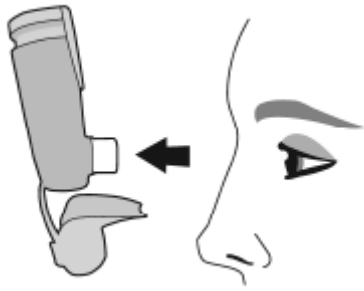


DAILY USE, morning & evening – Inhale your medicine

- **Daily Dose: 2 puffs in the morning and 2 puffs in the evening.**
- Rinse mouth with water after the 2 puffs to prevent fungal infection.

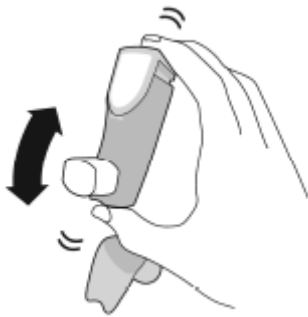
Step 1

Remove mouthpiece cover. **Check the mouthpiece for foreign objects and remove objects before use.**



Step 2

- Shake the inhaler well before each puff.



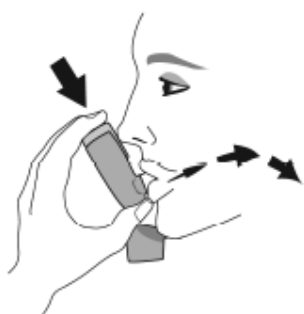
- Breathe out fully.



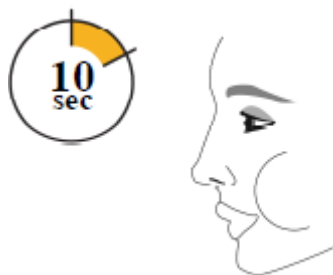
- Place mouthpiece into mouth and close lips around the mouthpiece.



- Start to breathe in deeply and slowly while spraying **1 puff**. Continue breathing in until you cannot any more.



- Hold breath for as long as you can, up to **10 seconds**.

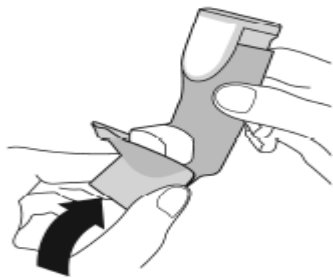


Step 3



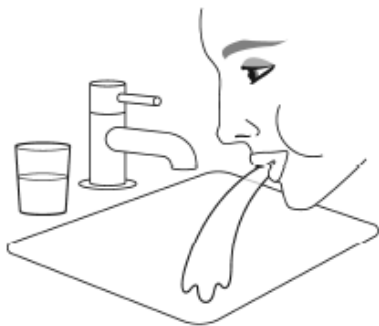
Step 4

Put mouthpiece cover back on



Step 5

Rinse mouth with water. Spit out water. **Do not swallow.**

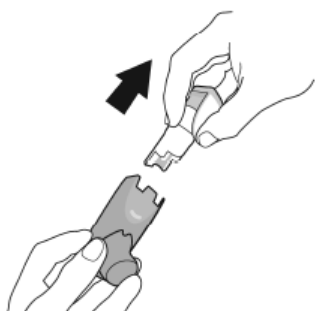


WEEKLY RINSE – Rinse your actuator once a week

- **Rinse yellow actuator weekly** so that medicine does not build up and block the spray through the mouthpiece.
- **Do not allow the canister to get wet.**
- **Re-prime after rinsing**

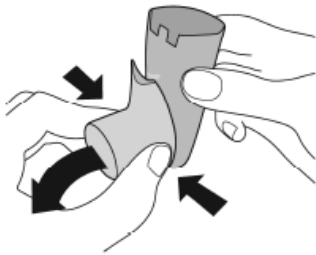
Rinse 1

Remove canister and set aside. **Do not allow the canister to get wet.**



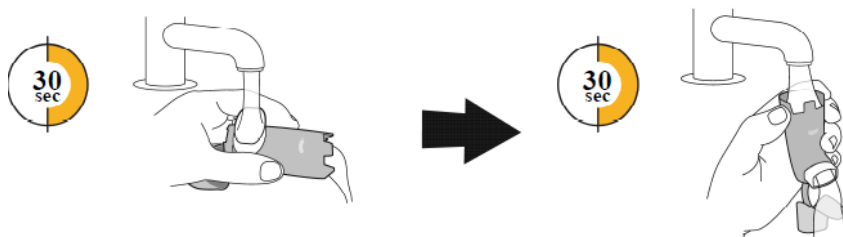
Rinse 2

Remove mouthpiece cover.



Rinse 3

Run warm water through the mouthpiece for 30 seconds and then through the top of the actuator for 30 seconds. **Rinse for 60 seconds in total.**



Rinse 4

Shake off as much water as you can.



Do not dry with a towel or tissue.

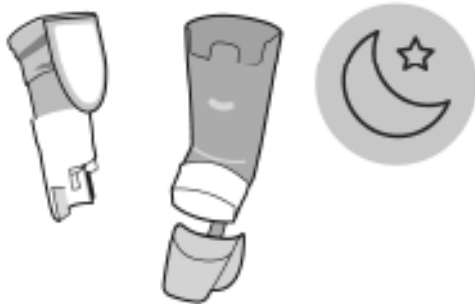
Rinse 5

Look into the actuator and mouthpiece for medicine build-up. If there is any build-up, repeat steps Rinse 3 through 5.



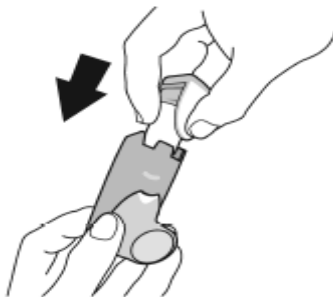
Rinse 6

Air-dry, preferably overnight. Do not put the canister back into the actuator if it is still wet.



Rinse 7

When dry, **replace the mouthpiece cover first** and then gently press the canister down into the actuator.



Rinse 8

Re-prime the inhaler by spraying 2 **Test-puffs**, shaking before each Test-puff.

**x2 total
Shake and
Test-puffs**