Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr BREZTRI® AEROSPHERE®

budesonide / glycopyrronium / formoterol fumarate dihydrate pressurized inhalation suspension

This Patient Medication Information is written for the person who will be taking **BREZTRI® AEROSPHERE®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **BREZTRI AEROSPHERE**, talk to a healthcare professional.

What BREZTRI AEROSPHERE is used for:

Chronic Obstructive Pulmonary Disease (COPD):
BREZTRI AEROSPHERE 160 mcg / 7.2 mcg / 5 mcg is used in adults for the long-term treatment of a lung disease called chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

BREZTRI AEROSPHERE is used to make breathing easier and help prevent worsening of COPD symptoms ("flare ups"). You may experience "flare-ups" during which your symptoms become worse. If you have a history of experiencing "flare-ups" BREZTRI AEROSPHERE can help prevent them from developing in the first place.

Asthma:
BREZTRI AEROSPHERE 160 mcg / 14.4 mcg / 5 mcg is used for the maintenance treatment of asthma in adults and adolescents (12 years of age and older) whose asthma is not being adequately controlled with a maintenance combination of a medium or high dose inhaled corticosteroid and a long-acting $beta_2$-agonist.

How BREZTRI AEROSPHERE works:

BREZTRI AEROSPHERE contains 3 medicinal ingredients:

- budesonide is an inhaled corticosteroid (ICS).
- glycopyrronium is a long-acting muscarinic antagonist (LAMA).
- formoterol fumarate dihydrate is a long-acting $beta_2$ agonist (LABA).

Budesonide belongs to a group of medicines called corticosteroids. It reduces inflammation in the airways of your lungs, which can ease breathing problems, and help prevent "flare-ups" of your COPD or asthma attacks. Glycopyrronium and formoterol fumarate dihydrate belong to a group of medicines called bronchodilators. These two medicines work together to help open and relax the muscles of the airways. This allows more air to get in and out of the lungs. This makes it easier for people with COPD or asthma to breathe and helps prevent shortness of breath and wheezing. BREZTRI AEROSPHERE is not a cure for COPD or asthma, but it can help to control it. Therefore, it is important to continue to take it regularly, even if you feel fine.

The ingredients in BREZTRI AEROSPHERE are:

Medicinal ingredients: budesonide, glycopyrronium (as bromide), and formoterol fumarate dihydrate

Non-medicinal ingredients: hydrofluoroalkane (HFA-134a), porous particles (comprised of: 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) and calcium chloride).

BREZTRI AEROSPHERE comes in the following dosage forms:

Pressurized inhalation suspension in a metered dose inhaler (for oral inhalation) that delivers:

- 160 mcg budesonide / 7.2 mcg glycopyrronium (as bromide) / 5 mcg formoterol fumarate dihydrate per actuation.
- 160 mcg budesonide / 14.4 mcg glycopyrronium (as bromide) / 5 mcg formoterol fumarate dihydrate per actuation.

Do not use BREZTRI AEROSPHERE:

- if you are allergic to budesonide, glycopyrronium, formoterol fumarate dihydrate or any of the other ingredients of BREZTRI AEROSPHERE;
- to treat sudden severe symptoms of COPD or asthma, such as shortness of breath or wheezing. Always have a rescue inhaler with you to treat sudden symptoms ("flare ups"). If you do not have a rescue inhaler, ask your healthcare professional to prescribe one for you.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BREZTRI AEROSPHERE. Talk about any health conditions or problems you may have, including if you:

- are a smoker. It is important to quit smoking if you use BREZTRI AEROSPHERE, this will help decrease the symptoms of COPD and asthma and may increase your lifespan;
- are using a rescue inhaler on a regular basis;
- have heart problems, such as:
  - heart disease
  - rapid or irregular heart beat or any problems with how your heart beats
  - a condition called "QT prolongation"
- have high blood pressure;
- have eye problems such as increased pressure in the eye, glaucoma, cataracts, blurry vision or other changes in vision;
- have prostate or bladder problems, or any problems passing urine;
- used to take 20 mg or more of prednisone per day;
- have or are at risk for decreased bone mineral content;
- have ever had seizures;
- have problems with your thyroid gland;
- have diabetes;
- have ever had to stop taking another medication for your breathing problems because you were allergic to it or it caused problems;
- have been taking other corticosteroids by mouth or by inhalation;
- have any allergies to food or drugs;

- have or have a history of lung infections such as pneumonia (if you have COPD);
- have low levels of potassium in your blood;
- have kidney or liver problems;
- have or have ever had tuberculosis;
- have chronic or untreated infections:
  - bacterial infection
  - viral infection
  - fungal infection (yeast infection or thrush)
  - parasitic infection
  - herpes simplex infection of the eye
- are pregnant or trying to become pregnant. Your healthcare professional will consider the benefit to you and the risk to your unborn baby;
- are breastfeeding or planning to breastfeed.

Other warnings you should know about:

Do not stop taking BREZTRI AEROSPHERE without talking to your healthcare professional first. If you stop treatment on your own, your symptoms may worsen. Talk to your healthcare professional **right away** if:

- there is a change in your symptoms such as more coughing, wheezing, chest tightness or breathlessness;
- you find that you need to use your rescue inhaler more often than usual.

These could be warning signs that your condition may be getting worse.

Paradoxical bronchospasm: if you feel tightness of the chest, coughing, wheezing or breathlessness right after using BREZTRI AEROSPHERE, you may have a serious condition called “paradoxical bronchospasm” (an unexpected closing of your airways). Stop using BREZTRI AEROSPHERE and seek medical help right away.

Monitoring: During treatment with BREZTRI AEROSPHERE, your healthcare professional may monitor:

- your bones and eyes;
- the effects of corticosteroid therapy on your body;
- your blood sugar levels, especially if you have diabetes;
- your blood potassium levels, especially if you already have low levels of potassium.

Eye problems: BREZTRI AEROSPHERE can cause eye disorders such as:

- cataracts: clouding of the lens in the eye, blurry vision, eye pain;
- glaucoma: an increased pressure in your eyes, eye pain, halos around lights or coloured images, red eyes. Untreated, it may lead to permanent vision loss.

If you have any changes in your vision, tell your healthcare professional **right away**. You may need regular eye exams.

Chicken pox and measles: You should avoid exposure to chicken pox and measles, and tell your healthcare professional if you are exposed. This is important if you are taking any cortisone-type medicine and your immune system is not working well (if you have difficulty in fighting an infection).

Eosinophilic granulomatosis with polyangiitis (EGPA): Some people experience a flu-like illness called EGPA when taking an inhaled corticosteroid. Tell your healthcare professional if you have:

- a rash,
- pins and needles or numbness of your arms or legs,
- a severe sinus infection and
- worsening lung or breathing problems.

Driving and using machines: BREZTRI AEROSPHERE can cause headaches, or nausea which may affect your ability to drive and use machines. Use caution when driving and using machines until you know how BREZTRI AEROSPHERE affects you.

Slowed growth in adolescents. If you are an adolescent with asthma, your growth should be checked regularly by your healthcare professional while you are using BREZTRI AEROSPHERE.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BREZTRI AEROSPHERE:

- 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, nelfinavir or cobicistat, to treat HIV infection;
- oral corticosteroids such as prednisone;
- medicines that lower the amount of potassium in your blood, such as some diuretics (“water pills”);
- other long-acting medicines similar to this medicine that are used to treat breathing problems, such as medicines containing tiotropium, ipratropium, aclidinium, umeclidinium or salmeterol, arformoterol, vilanterol, olodaterol or indacaterol;
- medicines which are used to treat heart rhythm problems, such as amiodarone;
- medicines used in the treatment of depression (antidepressants or monoamine oxidase inhibitors);
- medicines called “anticholinergics”.

Ask your healthcare professional if you are not sure. The use of BREZTRI AEROSPHERE with these medicines is not recommended.

How to take BREZTRI AEROSPHERE:

- Read the Instructions for Use for instructions on how to use BREZTRI AEROSPHERE. If you have any questions, talk to your healthcare professional.

- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- Take BREZTRI AEROSPHERE exactly as your healthcare professional tells you to.
- Take every day as prescribed, even if you have no symptoms of COPD or asthma.
- After you take your dose, always rinse your mouth with water and spit it out, do not swallow.

Usual dose:

If you have COPD

Adults (aged 18 years and over): The recommended dose is 2 oral inhalations (puffs) of BREZTRI AEROSPHERE 160 mcg / 7.2 mcg / 5 mcg taken twice daily, in the morning and evening

If you have asthma

Adults and adolescents (12 years of age and over): The recommended dose is 2 oral inhalations (puffs) of BREZTRI AEROSPHERE 160 mcg / 14.4 mcg / 5 mcg taken twice daily, in the morning and evening.

Always carry your separate rescue inhaler with you to treat sudden asthma symptoms when they happen. It is important that you contact your healthcare professional if you find the treatment ineffective at the recommended dose.

Using BREZTRI AEROSPHERE with a spacer:

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

Overdose:

Signs of an overdosage may include:

- blurred vision;
- dry mouth;
- nausea;
- muscle spasm;
- tremor;
- headache;
- increased heart rate; and
- increased blood pressure.

If you think you, or a person you are caring for, have taken too much BREZTRI AEROSPHERE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

Do not take a double dose to make up for a forgotten dose. If you miss a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose and go

back to your regular dosing schedule. Do not take more than 2 puffs twice a day.

Possible side effects from using BREZTRI AEROSPHERE:

These are not all the possible side effects you may have when taking BREZTRI AEROSPHERE. If you experience any side effects not listed here, tell your healthcare professional.

- feeling anxious;
- trouble sleeping;
- headache;
- feeling sick (nausea);
- cough and/or a hoarse voice;
- muscle spasms;
- shaking/tremors;
- dry mouth;
- mild irritation in the throat;
- bruising of the skin;
- feeling restless, nervous or agitated;
- feeling dizzy;
- changes in behaviour.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Hyperglycemia (high blood sugar): increased thirst, frequent urination, headache, blurred vision and fatigue		✓	
Palpitation (fast-beating, fluttering or pounding heart): skipping beats, beating too fast, pounding, fluttering rapidly		✓	
Pneumonia (infection in the lungs) (in COPD patients): chest pain when you breathe or cough, confusion, cough which may produce phlegm, fatigue,		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
fever, sweating and shaking, chills, shortness of breath			
Thrush (yeast infection of the mouth or throat): thick white patches in the mouth, tongue or on the throat, sore throat		✓	
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong smelling urine, cloudy urine		✓	
Uncommon			
Allergic Reaction: difficulty swallowing or breathing, wheezing, feeling weak or light headed, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓
Angina (not enough oxygen to the heart muscle): discomfort in the shoulder, arm, back, throat, jaw or teeth; pain or pressure in the chest		✓	
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heart beat		✓	
Bronchospasm (when there is a sudden narrowing of the airway): difficulty breathing with wheezing or coughing			✓
Depression (sad mood that won't go away)**:** difficulty sleeping or sleeping too much,		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced sex drive and thoughts of death or suicide. If you have a history of depression, your depression may become worse			
Tachycardia (abnormally fast heart beat): dizziness, light headedness, shortness of breath, racing heart		✓	
Urinary retention (inability to pass urine or to empty the bladder): painful urination, pain or swelling in the lower abdomen		✓	
Very rare			
Decreased Adrenal Function: tiredness, weakness, nausea and vomiting, low blood pressure	✓		
Unknown			
Cataracts: clouding of the lens in the eye, blurry vision, dim vision and/or eye pain		✓	
Glaucoma: increased pressure in your eyes, eye and head pain, swelling or redness in or around the eye, changes in vision, hazy or blurred vision, sudden sight loss		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15 to 30°C. Store in a dry place.

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 and protect from freezing temperatures. If exposed to freezing temperatures, the inhaler should be equilibrated for 1 hour at room temperature prior to taking a dose.

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

After opening the pouch, the inhaler must be used within:

- 6 weeks for an inhaler that contains 56 actuations;
- 3 months for an inhaler that contains 120 actuations.

Dispose of your inhaler after the last dose, following local guidelines. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

Keep out of reach and sight of children.

If you want more information about BREZTRI AEROSPHERE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.astrazeneca.ca, or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

This leaflet was prepared by AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4

Date of Authorization: 2026-11-16

BREZTRI®, AEROSPHERE®, and the AstraZeneca logo are registered trademarks of AstraZeneca AB, all used under license by AstraZeneca Canada Inc.

AstraZeneca

Read prior to using inhaler

Instructions For Use

Pr BREZTRI® AEROSPHERE®

budesonide / glycopyrronium / formoterol fumarate dihydrate pressurized inhalation suspension

Please read these instructions carefully.

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

Watch our video to make sure you use BREZTRI AEROSPHERE correctly.

www.breztri.ca/video

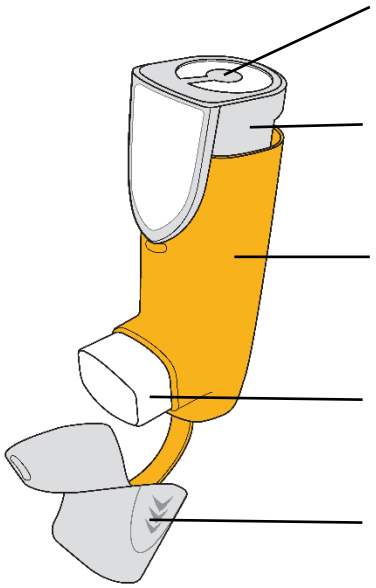
Important Information

- **For oral inhalation use only**
- **Prime your BREZTRI AEROSPHERE inhaler before using it for the first time**
- **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 between 15°C to 30°C, in a dry place
- **Do not store in a humid environment, such as a bathroom**
- Keep your inhaler and all medicines out of the reach and sight of children

Parts of your inhaler



Puff indicator
Attached to the top of the pressurized canister.

Pressurized Canister (inside)
Holds the medicine.

Actuator
Contains the pressurized canister.

Mouthpiece
Sprays the medicine.

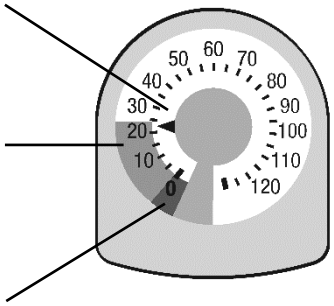
Mouthpiece cover
Protects the mouthpiece when the inhaler is not in use.

Reading the puff indicator

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

The display window for the 30-day inhaler shows 120 and the 14-day inhaler shows 60.

ⓘ **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:

- The puff indicator shows 0

or

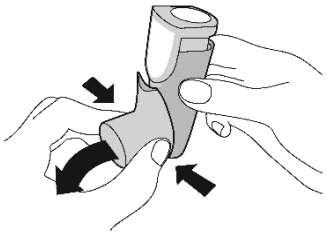
- **3 months** (for the 30-day inhaler) or **6 weeks** (for the 14-day inhaler) after your inhaler has been removed from the foil pouch

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.

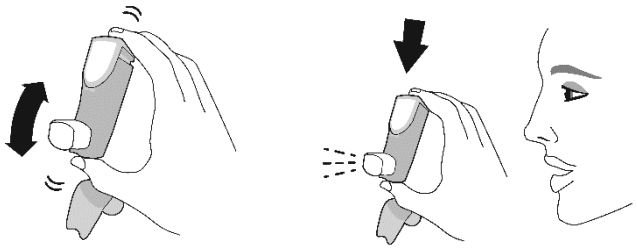
BEFORE FIRST USE – Prime your inhaler 4 times before first use

- 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 by squeezing both sides and pulling out. 

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.

x4 total
Shake and Test-puffs



ⓘ 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 re-prime, spray **2 Test-puffs**, shaking before each Test-puff.

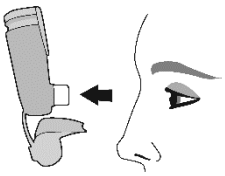
x2 total
Shake and Test-puffs

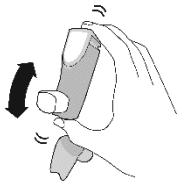
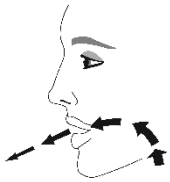
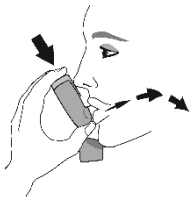
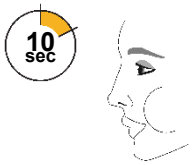
DAILY USE, morning & evening – Inhale your medicine

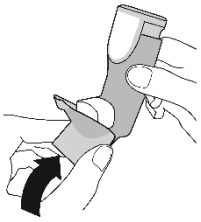
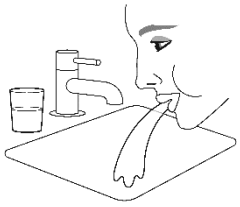
- **Daily Dose: 2 puffs in the morning and 2 puffs in the evening.**
- Rinse mouth with water after the 2 puffs to prevent fungal infection.

Step 1

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

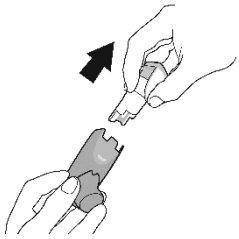
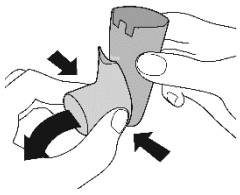


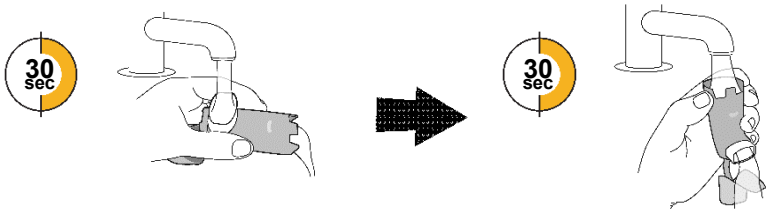
Step 2				
Shake the inhaler well before each puff. 	Breathe out fully. 	Place mouthpiece into mouth and close lips around the mouthpiece. 	Start to breathe in deeply and slowly while spraying **1 puff**. Continue breathing in until you cannot any more. 	Hold breath for as long as you can, up to **10 seconds.** 

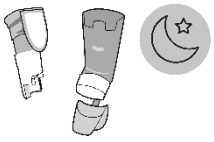
Step 3	Step 4	Step 5
	Put mouthpiece cover back on. 	Rinse mouth with water. Spit out water. **Do not swallow.** 

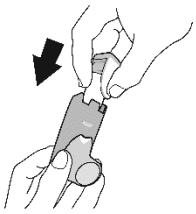
WEEKLY RINSE – Rinse your actuator once a week

- **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	Rinse 2
Remove canister and set aside. **Do not allow the canister to get wet.** 	Remove mouthpiece cover. 

Rinse 3	Rinse 4
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.** 	**Shake off as much water as you can.**  **Do not dry with a towel or tissue.**

Rinse 5	Rinse 6
Look into the actuator and mouthpiece for medicine build-up. If there is any build-up, repeat steps Rinse 3 through 5. 	Air-dry, preferably overnight. **Do not** put the canister back into the actuator if it is still wet. 

Rinse 7	Rinse 8
When dry, **replace the mouthpiece cover first** and then gently press the canister down into the actuator. 	Re-prime the inhaler by spraying **2 Test-puffs,** shaking before each Test-puff. **x2 total Shake and Test-puffs**

BREZTRI®, AEROSPHERE®, and the AstraZeneca logo are registered trademarks of AstraZeneca AB, all used under license by AstraZeneca Canada Inc.

Date of Authorization: 2026-11-16