

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

PrMYLAN-BUDESONIDE AQ
Budesonide Aqueous Nasal Spray

Read this carefully before you start taking MYLAN-BUDESONIDE AQ and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MYLAN-BUDESONIDE AQ.

What is MYLAN-BUDESONIDE AQ used for?

- seasonal allergic rhinitis (hay fever) and perennial (year-round) rhinitis in patients 6 years and older
- nasal polyps and to prevent new nasal polyps from appearing after surgery (polypectomy) in patients 12 years and older.

How does MYLAN-BUDESONIDE AQ work?

MYLAN-BUDESONIDE AQ reduces and prevents inflammation in the lining of the nose (rhinitis).

What are the ingredients in MYLAN-BUDESONIDE AQ?

Medicinal ingredient: Budesonide

Non-medicinal ingredients: Dextrose, Disodium Edetate, Hydrochloric Acid, Microcrystalline Cellulose, Carboxymethylcellulose sodium, Potassium Sorbate, Tween 80 and Water.

MYLAN-BUDESONIDE AQ comes in the following dosage forms:

MYLAN-BUDESONIDE AQ comes as a nasal spray: 100 mcg of budesonide per spray. The bottle will deliver 165 sprays.

Do not use MYLAN-BUDESONIDE AQ if you:

- are allergic to budesonide or any of the other ingredients;
- have an untreated fungal (yeast), bacterial or viral infection;
- have or have had tuberculosis;
- are under the age of 6 years.

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

- have or have had any other recent infection. MYLAN-BUDESONIDE AQ may hide some symptoms of infection or may cause the symptoms of infection to worsen. You may be more likely to get an infection while taking MYLAN-BUDESONIDE AQ
- have asthma;
- have thyroid problems;
- have open wounds after recent nasal surgery or trauma
- have or had liver problems;
- are on drugs that suppress the immune system;
- have ever been diagnosed with glaucoma, cataracts or have an eye infection, or if you have diabetes;
- are taking, or have previously taken steroids either as an injection or by mouth within the past several months;
- are pregnant or planning to become pregnant. MYLAN-BUDESONIDE AQ should only be used during pregnancy if the potential benefits to the mother outweigh the risk to the unborn baby.
- are breastfeeding. Budesonide will transfer to the mother's breast milk. It should only be used if the benefit to the mother outweighs the potential risk to the baby.
- have a rare blood disorder called hypoprothrombinemia.

Other warnings you should know about:

Local corticosteroids such as MYLAN-BUDESONIDE AQ may cause:

- slower growth in children. Continuous long-term use in children is not recommended as the effects are not fully known. Talk to your child's physician if your child needs to use the spray for longer than two months a year. Your child's doctor should regularly monitor their growth while they are taking MYLAN-BUDESONIDE AQ.
- symptoms of Cushing's syndrome, such as thinning fragile skin that bruises easily, rapid weight gain around the body and face, excess sweating, and muscle and bone weakness.
- development of unintentional and purposeless motions and restlessness, sleep disorders, anxiety, depression and aggression.

Changes in vision

Changes in vision can occur with the use of corticosteroids. The changes can include:

- Cataracts: clouding of the lens in the eye, blurry vision, eye pain;
- Glaucoma: an increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss;
- Central serous chorioretinopathy (CSCR): blurry vision or other changes in your vision.

If you notice any changes in your vision while taking MYLAN-BUDESONIDE AQ, tell your doctor right away. Your doctor may monitor your eyes during your treatment.

Exposure to measles or chicken pox:

You should avoid coming into contact with people who have measles or chicken pox while taking MYLAN-BUDESONIDE AQ. If you are exposed, tell your doctor right away.

Transfer to MYLAN-BUDESONIDE AQ from an oral corticosteroid

If you have been prescribed MYLAN-BUDESONIDE AQ and are taking oral steroid medication, your doctor may gradually reduce the dose of your tablets. This may happen over a period of weeks or months.

You should contact your doctor if you get symptoms such as:

- headache
- tiredness
- muscle and joint pain
- nausea or vomiting
- depression
- rash
- runny nose
- coughing, especially at night, during exercise or when laughing
- difficulty breathing
- chest tightness
- shortness of breath
- wheezing.

Tell your doctor if:

- your symptoms have not improved after 2 weeks of taking MYLAN-BUDESONIDE AQ
- your nose becomes irritated or you have severe or frequent nose bleeds
- you develop signs or symptoms of an infection such as persistent fever
- you have a yellow or green discharge from your nose

If symptoms persist or worsen, or if new symptoms occur, stop use and consult a doctor.

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

The following drugs may interact with MYLAN-BUDESONIDE AQ:

- ritonavir, atazanavir, indinavir, nelfinavir, saquinavir and cobicistat-containing products used to treat HIV or AIDS
- ketoconazole, itraconazole used to treat fungal infections
- clarithromycin, telithromycin used to treat bacterial infections
- nefazodone used to treat depression

How to take MYLAN-BUDESONIDE AQ

- MYLAN-BUDESONIDE AQ is for use in the nose only. **Do not** use it in your eyes or mouth.
- It may take 2-3 days (and up to 2 weeks) to work. Take it each day without missing a dose to get the best results.
- It works best if it is started before allergy season begins.

- It does not relieve allergy symptoms in the eyes. Tell your doctor if your eyes bother you and they can give you additional medicine to help.
- If your nose is blocked, you can use decongestant nose drops during the first 2-3 days of the treatment.
- Stop taking MYLAN-BUDESONIDE AQ if it does not relieve your symptoms after 3 weeks of regular treatment.

Take MYLAN-BUDESONIDE AQ exactly as recommended by your doctor. **Follow your doctor's directions carefully. They may differ from the information in this leaflet.**

Do not stop taking MYLAN-BUDESONIDE AQ unless your doctor told you to, even if you feel better. Do not stop treatment with MYLAN-BUDESONIDE AQ abruptly, it should be tapered off gradually.

Always supervise children when they are using MYLAN-BUDESONIDE AQ. This will help them get the correct dose.

Usual dose:

Depending on how MYLAN-BUDESONIDE AQ works for you, your doctor may change your dose.

Rhinitis in patients 12 years and older:

MYLAN-BUDESONIDE AQ can be taken once a day or twice a day.

- **Usual once a day starting dose:** 2 sprays into each nostril once a day (in the morning)
- **Usual twice a day starting dose:** 1 spray into each nostril twice a day (in the morning and evening)
- **Maintenance dose:** Use the lowest effective dose necessary to control symptoms. The usual maintenance dose is 1 spray into each nostril in the morning only.

Rhinitis in patients 6 to 11 years of age:

- **Usual dose:** 1 spray into each nostril once a day (in the morning)
- If symptoms do not improve, 2 sprays per nostril once a day (in the morning) can be used.
- **Maintenance dose:** Once allergy symptoms improve, the maintenance dose is 1 spray in each nostril once daily in the morning.

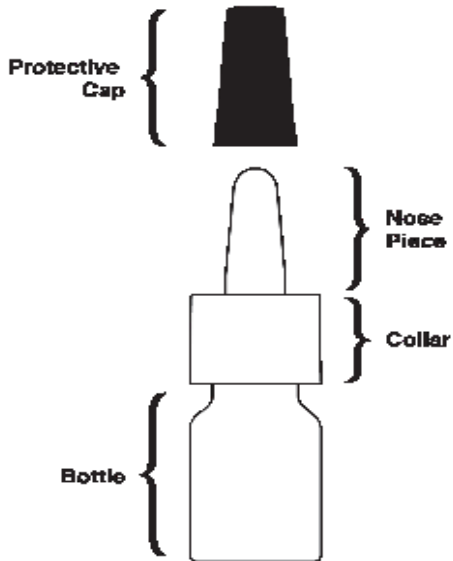
Nasal Polyps in patients 12 years and older:

Usual Dose: 1 spray into each nostril twice a day (in the morning and evening).

How to use your MYLAN-BUDESONIDE AQ

Before you start using MYLAN-BUDESONIDE AQ for the first time, it is important that you read the instructions below and follow them carefully.

Parts of the Spray Bottle:



A. Before using MYLAN-BUDESONIDE AQ for the first time:

You must prepare MYLAN-BUDESONIDE AQ before you use it. Follow the steps below:

- 1 Turn the bottle upside-down 3 to 4 times. Remove the protective cap from the nose piece.
- 2 Load the pump by pressing downwards on the collar. Use your index and middle fingers while supporting the base of the bottle with your thumb (Figure 1). Press down 5 to 10 times away from the face until a fine mist spray appears. Avoid spraying the mist in your eyes.



Figure 1

The spray is now ready for use.

B. How to take a dose:

Follow these instructions for daily use of MYLAN-BUDESONIDE AQ:

- 1 Turn the bottle upside-down 3 to 4 times. Remove the protective cap from the nose piece.
- 2 If you did not use your spray yesterday, make sure you prepare the pump by pressing down once only (Figure 1). Avoid spraying the mist in your eyes.
- 3 Gently blow your nose. Hold the bottle as shown. Tilt your head forward slightly. Close one nostril with a finger and gently insert the tip of the nose piece into the other nostril (Figure 2).



Figure 2

- 4 For each spray your doctor has instructed you to take, press firmly downwards once on the collar. Breathe gently inwards through the nostril, then breathe out through the mouth.
- 5 Repeat the procedure for the other nostril.
- 6 Replace the protective cap on the nose piece. Keep the bottle in an upright position.

C. How to clean MYLAN-BUDESONIDE AQ

Clean the nose piece and protective cap regularly. To clean the nose piece, remove the protective cap, press upwards on the collar and the nose piece will come off. Wash the nose piece and protective cap under lukewarm water. Air dry and replace the nose piece and the protective cap back on the bottle and reload as in Step #2. **Do not try to clean the nasal applicator by using a pin or sharp object.**

Overdose:

If you think you have taken too much MYLAN-BUDESONIDE AQ, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose take it as soon as possible. Then go back to your regular schedule.
- If it is almost time to take your next dose, skip the missed dose and take the next dose at the usual time.
- **Do NOT take a double dose of MYLAN-BUDESONIDE AQ to make up for a missed dose.** If you are still unsure, check with your doctor or pharmacist to see what you should do.

What are possible side effects from using MYLAN-BUDESONIDE AQ

These are not all the possible side effects you may feel when taking MYLAN-BUDESONIDE AQ. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects are:

- nose and throat irritation,
- nose bleeding and crusting
- stomach pain
- ear, nose and/or throat infection
- rash

Other side effects include:

- itchy and sore throat
- cough
- fatigue
- nausea/dizziness
- headache

Uncommon side effects that may occur when also taking an oral steroid:

- asthma
- skin rash
- itching or swelling in the face
- Cushing’s syndrome (hypercorticism)
- small holes or ulcers in the skin inside the nose

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	

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Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Uncommon	Cushing's Syndrome: (hypercorticism) Rapid weight gain especially around the body and face; round "moon" face, Excess sweating; thinning of the skin with easy bruising and dryness; muscle and bone weakness		X	
Very rare	Small holes or ulcers in the skin inside the nose		X	
	Allergic reactions, including Anaphylactic reactions: such as swelling of the face, lips, tongue, and/or throat (which may cause difficulty in breathing or swallowing), hives, rash and itching			X
Unknown	Cataracts: glare, reduced vision		X	
	Glaucoma: increased pressure in your eyes, eye pain			X
	Nasal perforation: constant whistling sound when you breathe from your nose			X
	Vision blurred			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

Keep MYLAN-BUDESONIDE AQ out of the reach and sight of children.

Store the bottle at room temperature (15°C - 30°C). Always replace the protective cap after using MYLAN-BUDESONIDE AQ.

Do not keep or use MYLAN-BUDESONIDE AQ after the expiry date indicated on the label.

If you want more information about Mylan-Budesonide AQ:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); or by calling 1-844-596-9526

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