

PART III: CONSUMER INFORMATION

DYMISTA®

Azelastine Hydrochloride and Fluticasone Propionate Suspension
Nasal Spray

137 mcg/50 mcg per metered spray

This leaflet is part III of a three-part "Product Monograph" published when DYMISTA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DYMISTA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

DYMISTA® is a prescription medicine used to treat symptoms of moderate to severe seasonal allergic rhinitis (allergy in the nose) and related eye symptoms in patients 12 years of age and older who need treatment with both azelastine hydrochloride and fluticasone propionate.

What it does:

DYMISTA helps reduce the symptoms of seasonal allergic rhinitis (inflammation of the lining of the nose), such as stuffy nose, runny nose, itching, sneezing, eye redness, itchy and watery eyes.

When it should not be used:

- if you are allergic to any of the ingredients in DYMISTA,
- if you have untreated fungal, bacterial, or tuberculosis infections of the respiratory tract.

What the medicinal ingredients are:

- azelastine hydrochloride
- fluticasone propionate

What the nonmedicinal ingredients are:

disodium edetate, glycerol, microcrystalline cellulose and carmellose sodium, polysorbate 80, benzalkonium chloride, phenylethyl alcohol and purified water.

What dosage forms it comes in:

Suspension for metered spray: 137 micrograms of azelastine hydrochloride and 50 micrograms of fluticasone propionate per spray.

WARNINGS AND PRECAUTIONS

BEFORE you start taking DYMISTA, talk to your doctor or pharmacist if you:

- Are pregnant (or planning to become pregnant). It is not known if DYMISTA will harm your unborn baby.
- Are breastfeeding or plan to breast-feed. It is not known if DYMISTA passes into your breast milk.
- Are allergic to any other corticosteroid or medications.
- Have green or yellow discharge from the nose.
- Have eye or vision problems, such as cataracts or glaucoma (increased pressure in your eye).
- Are taking other steroid medicine by mouth or as an injection.
- Are recovering from recent nasal surgery, nasal trauma or nasal ulcers.
- Have been near someone who has chickenpox or measles.
- Have a problem with your thyroid.
- Suffer from liver disease.

You should avoid coming into contact with measles or chickenpox while taking DYMISTA. If you are exposed, tell your doctor.

Drugs like DYMISTA can cause eye disorders:

- 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.
- You should have regular eye exams.

INTERACTIONS WITH THIS MEDICATION

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. DYMISTA may affect the way other medicines work, and other medicines may affect how DYMISTA works.

In particular tell your healthcare provider before taking DYMISTA, if you are taking or have recently taken:

- ritonavir or cobicistat-containing products (commonly used to treat HIV infection or AIDS). Your healthcare provider may wish to monitor you carefully if you are taking these medicines.
- ketoconazole (for fungal infections).
- cimetidine (inhibits stomach acid production).
- Acetylsalicylic acid (ASA) and you have a blood clotting problem.

Rarely, DYMISTA can cause sleepiness or drowsiness. These may also be caused by the disease itself. Do not drive, operate machinery, or do anything that needs you to be alert until you know how DYMISTA affects you. Do not drink alcohol or take any other medicines that may cause you to feel sleepy while using DYMISTA.

PROPER USE OF THIS MEDICATION

DYMISTA is for use in your nose only. **Do not spray it into your eyes or mouth. If you spray DYMISTA Nasal Spray into your eye(s), flush your eye(s) with large amounts of water for 10 minutes and then call your doctor.** Use DYMISTA Nasal Spray exactly as recommended by your healthcare provider.

DYMISTA relieves the symptoms within 30 minutes. However, you will get the best results if you keep using DYMISTA regularly.

Do not prick the nozzle in case spray is not obtained. Clean the actuator with water.

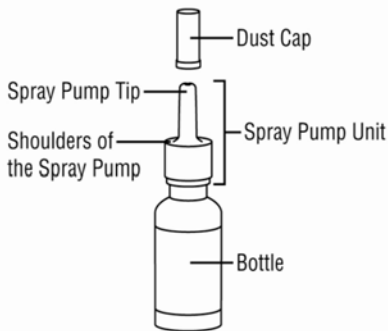
Usual dose:

Adults and Adolescents (12 Years and Older): One spray in each nostril twice daily (morning and evening).

Preparing the spray

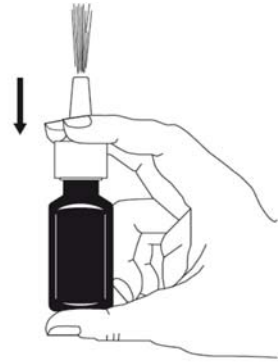
1. Shake the bottle gently until no residue is observed at the bottom of the bottle and then remove the protective cap (see Figure 1).

Figure 1



2. The first time the nasal spray is used, you must prime the pump.
- Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
 - Press down and release the pump 6 times into the air away from your face until a fine mist appears (see Figure 2).
 - Now your pump is primed and ready to use.

Figure 2



3. If the nasal spray has not been used for more than 7 days, you will need to prime the pump until a fine mist appears again.

Using the spray

1. Blow your nose to clear your nostrils.



2. Keep your head tilted downwards towards your toes. **Do not tilt head backwards.**

3. Hold the bottle upright and carefully insert the spray tip into one nostril.

4. Close other nostril with your finger, rapidly press down once on the spray pump and sniff gently at the same time (see Figure 3).

5. Breathe out through your mouth.

Figure 3



6. Repeat in your other nostril.

7. Breathe in gently, and **do not tilt your head back after dosing.** This will stop the medicine going into your throat and causing an unpleasant taste (see Figure 4).

Figure 4



8. After each use wipe the spray tip with a clean tissue or cloth and then replace the protective cap.

It is important that you take your dose as advised by your doctor. You should use only as much as your doctor recommends.

You may experience a bitter taste in your mouth, especially if you tilt your head backwards when you are using the nasal spray. This is normal. This should go away if you have a soft drink a few minutes after using this medicine. Occasionally you may sneeze a little after using this spray but this soon stops. You may experience an unpleasant smell.

To Clean the Spray Pump Tip:

Your DYMISTA Nasal Spray should be cleaned at least 1 time each week.

1. Remove the dust cap and then gently pull upward on the spray pump unit to remove it from the bottle. (See Figure 5)

Figure 5



2. Wash the spray pump unit and dust cap in warm tap water. (See Figure 6)

Figure 6



3. Allow to dry completely. When dry, place the spray pump unit

and dust cap back on the bottle. (See Figure 7)

Figure 7



4. If the spray pump unit becomes blocked, it can be removed as instructed above in Step 1 and placed in warm water to soak.

Do not try to unblock the spray pump unit by inserting a pin or other sharp object. This will damage the spray pump unit and cause you not to get the right dose of medicine.

5. After the spray pump unit is unblocked, rinse the applicator and cap with cold water, and allow them to dry as in Step 3 above. When dry, place the spray pump unit back on the bottle and put the dust cap on the spray pump tip.

6. Reprime the bottle as in **Preparing the spray** above. Replace the dust cap and your DYMISTA Nasal Spray is ready for use.

Overdose:

With the nasal route of administration overdose reactions are not anticipated.

If a child accidentally swallows DYMISTA Nasal Spray or you use too much DYMISTA Nasal Spray, call your doctor or go to the nearest hospital emergency room right away.

In case of accidental drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, take another dose as soon as you remember but if it is near to the time for the next dose, wait until it is due. Do not take a double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, DYMISTA may cause side effects in some people. Side effects that may occur with the use of antihistamine and corticosteroid nasal sprays, including DYMISTA, are:

- headache
- change in sense of taste and/or smell
- nose bleeds
- nasal ulcers; pain, burning, irritation
- crusting in the nose
- runny nose
- soreness or dryness in the inside of the nose
- sore throat, upper respiratory tract infection

- fever, cough, stuffy nose, chills, feeling tired
- sleepiness or drowsiness

If any of these affects you severely, tell your doctor, nurse or pharmacist.

Slower growth in adolescents (12-17 years of age) may occur with use of corticosteroid nasal sprays. Your physician should monitor your growth regularly if you are in this age group.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Rare	Cushing's Syndrome: rapid weight gain especially around the body and face; excess sweating; thinning of the skin with easy bruising and dryness; muscle and bone weakness.		✓	
	Decreased Adrenal Function: tiredness, weakness, nausea and vomiting.		✓	
	Osteonecrosis (tiny breaks in a bone leading to eventual collapse): Progressive or persistent pain or limited range of motion in a joint or limb.		✓	
	Cataracts: glare, reduced vision.		✓	
	Glaucoma: increased pressure in your eyes, eye pain.			✓
	Allergic Reactions: chest pain or tightness, wheezing, coughing or having difficulty breathing, suddenly feeling weak or lightheaded (which may lead to collapse or loss of consciousness), swelling around the face, mouth or tongue, eyes or lips with difficulty swallowing, skin rashes (hives) or redness.			✓
	Nose bleed	✓		
	Nasal Perforation: if you get a constant whistling sound when you breathe from your nose, it may be a symptom of nasal septal perforation.		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
	Infections: if you have worsening of the symptoms of infections such as existing tuberculosis, fungal, bacterial or parasitic infections or herpes of the eye.		✓
Unknown	Vision Blurred		✓

This is not a complete list of side effects. For any unexpected effects while taking DYMISTA, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your medicine in a safe place where children cannot reach it. Your medicine may harm them.

Store between 15 and 30°C. Do not freeze or refrigerate DYMISTA.

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 \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html\)](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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, BGP Pharma ULC at: 1-844-596-9526, www.mylan.ca.

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