

NEW ZEALAND CONSUMER MEDICINE INFORMATION

DYMISTA[®] NASAL SPRAY



What is in this leaflet

This leaflet answers some common questions about Dymista[®] Nasal Spray.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. **If you have any concerns about using this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine.

You may need to read it again.

What Dymista[®] Nasal Spray is used for

Dymista[®] Nasal Spray relieves the symptoms of allergies, for example: symptoms relating to the nose - runny nose, post nasal drip, sneezing, itchy or blocked nose and symptoms relating to the eyes - itchy, watery and red eyes.

Due to the fast relief and the anti-inflammatory effect, Dymista[®] Nasal Spray is more effective on symptoms relating to the nose and eyes than either antihistamine or corticosteroid therapy alone.

Dymista[®] Nasal Spray is sprayed into the nose to treat allergic rhinitis (hayfever and other allergies) and rhinoconjunctivitis (allergy-induced symptoms in the nose and eyes) in adults and children 12 years and older where use of a combination (intranasal antihistamine and glucocorticoid) is appropriate.

Hayfever is an inflammation or swelling of the nose lining (which may cause blockage, runny nose, itching and/or sneezing).

You may have symptoms only during spring or summer. This type of allergy is generally due to various pollens. Some people may experience symptoms all year round. This is usually caused by house dust mites, pets or moulds.

This medicine contains two active ingredients: azelastine hydrochloride and fluticasone propionate.

Azelastine hydrochloride belongs to a group of medicines called antihistamines. Antihistamines work by preventing the effects of substances such as histamine that the body produces as part of an allergic reaction. This reduces symptoms of an allergic rhinitis.

Fluticasone propionate belongs to a group of medicines called corticosteroids which are used to help reduce inflammation.

This medicine is available from pharmacies without a prescription.

Before you use Dymista[®] Nasal Spray

When you must not use it

Do not use the medicine if you have an allergy to azelastine hydrochloride or fluticasone propionate or any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction to a medicine may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 12 years.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Consult a healthcare professional before use if you have or have had any of the following medical conditions:

- Recent injury or surgery to your nose or mouth
- Infection in your nose or sinus
- Ulcer or open sores in your nose
- Active or inactive tuberculosis
- Severe liver disease
- Increased/ high pressure in the eye (glaucoma) and/ or cataracts.

Tell your pharmacist or doctor if you are pregnant or planning to become pregnant.

Your pharmacist or doctor can discuss with you the risks and benefits involved.

Tell your pharmacist or doctor if you are breast-feeding.

It is not known if Dymista[®] Nasal Spray passes into the breast milk and could affect your baby. Your pharmacist or doctor can discuss with you the benefits and risks involved with using this medicine while you are breast-feeding.

If you have not told your pharmacist or doctor about any

of the above, tell them before you start using the medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you can buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your pharmacist or doctor if you are taking:

- A medicine or medicines that depress the central nervous system. Concurrent use with Dymista® Nasal Spray may cause sleepiness or drowsiness.
- Ritonavir, an antiviral medicine
- Ketoconazole, an antifungal medicine
- Cimetidine, a medicine that inhibits stomach acid production.

These medicines may be affected by Dymista® Nasal Spray or may affect how well it works. You may need different amounts of your medicine, or you may need to use a different medicine. Your doctor or pharmacist will advise you.

Do not use Dymista® Nasal Spray with another steroid product, e.g. tablets, asthma or nasal inhaler, except on the advice of your healthcare professional.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Dymista® Nasal Spray

Use only in your nose.

Start using this medicine early to help reduce the severity of your symptoms:

- before the hayfever season, or
- before coming in contact with something you know will cause your hayfever.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

5 STEPS TO USE Dymista®

Dymista® is for use in your nose only. Do not spray Dymista® in your eyes. Before you use Dymista® Nasal Spray for the first time, you will need to prime the bottle.

1 SHAKE
Before you prime the bottle, shake it gently.

Remove the clear plastic dust cap from the spray pump tip of the bottle.

SHAKE GENTLY

REMOVE CAP

2 PRIME
Hold bottle upright with 2 fingers on the shoulders of the spray pump and your thumb on the bottom of bottle.

Press upward with your thumb and release. Repeat pumping action.

SPRAY PUMP SHOULDERS

BOTTLE BOTTOM

FINE MIST

PUMP BOTTLE UP TO 6 TIMES

Once you see a fine mist, your Dymista® Nasal Spray is ready to use.

3 CLEAR
Blow your nose to clear nostrils.

Shake the bottle gently.

SHAKE GENTLY

4 INSERT
Close 1 nostril with a finger. Place spray pump tip 1/4 to 1/2 inch into your other nostril.

Tilt head forward slightly. Do not tilt head back.

CLOSE 1 NOSTRIL

INSERT PUMP TIP

SEPTUM

Do not spray directly onto the nasal septum (the wall between your 2 nostrils).

KEEP HEAD TILTED FORWARD

5 SPRAY & BREATHE
Keeping bottle upright, pump once firmly.

Repeat in other nostril.

As you spray, breathe in gently through the treated nostril.

REPEAT

Wipe off tip with clean tissue. Replace dust cap.

REPLACE DUST CAP

WIPE OFF TIP

If you do not use your spray for 14 or more days, you'll need to prime the pump with 1 spray, or until you see a fine mist. If you do not see a fine mist, clean the tip of the spray nozzle.

See **CLEANING INSTRUCTIONS**.

How much to use

Adults and children 12 years and older

One spray into each nostril in the morning and evening.

Do not use in children under 12 years.

Do not exceed the recommended dose.

How to use

Do not use Dymista® Nasal Spray for longer than six months except on the advice of a doctor or pharmacist.

If you forget to use

If you miss a dose, use Dymista® Nasal Spray when the next dose is due.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you have too much (Overdose)

If you or someone else accidentally uses too much Dymista® Nasal Spray on one occasion, there is nothing to worry about.

However, if you use too much of it over a long time (months or years), you may start to get unwanted side effects inside your nose and body.

Discuss any worries you may have about this with your doctor or pharmacist.

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 764766) if you or anyone else may have accidentally swallowed Dymista® Nasal Spray. Do this even if there are no signs or symptoms of discomfort or poisoning.

While you are using Dymista® Nasal Spray

Things you must do

Consult your doctor or pharmacist if the

symptoms/condition persist(s) for more than 7 days.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Consult your doctor or pharmacist if you develop signs/symptoms of nasal infection such as fever, facial pain or swelling, or discoloured nasal discharge.

Consult your doctor or pharmacist if your nose bleeds.

If you become pregnant while you are using this medicine, tell your doctor or pharmacist. Your doctor or pharmacist can discuss with you the risks of using it while you are pregnant.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Do not use it to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Make sure you know how you react to Dymista® Nasal Spray before you drive, operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed.

Dymista® Nasal Spray is unlikely to make you feel drowsy. However, if you are drowsy, do not drive a car or operate machinery.

Things that may be helpful

If possible, avoid situations that you know will trigger your symptoms.

To prevent symptoms, start using this medicine

- before the hayfever season, or
- before coming into contact with something you know will cause your hayfever.

If you start using this medicine early, it will help reduce the severity of your symptoms.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Dymista® Nasal Spray.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- irritated nose. This can cause mild stinging, itching or sneezing
- cough, dry throat or throat irritation
- sore throat
- nose bleeds
- nausea
- headache.

If you get a bitter taste in your mouth, it may be the way you are spraying; please check steps 4 & 5 again. If this continues please tell your pharmacist or doctor.

Consult a healthcare professional if you notice any of the following:

- sleepiness or drowsiness
- feeling weary, exhausted or weak
- damage of the skin and mucous membrane in the nose
- blurred vision, eye pain or increased pressure in your eye.

If any of the following happen, stop using Dymista® Nasal Spray and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Dymista® Nasal Spray

Storage

Keep Dymista® Nasal Spray in a cool dry place where the temperature stays below 25°C. Do not refrigerate or freeze this medicine.

Discard after 6 months of first opening the bottle.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep the medicine where young children cannot reach it.

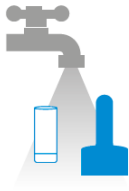
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

CLEANING INSTRUCTIONS

- 1 Once a week, remove the dust cap. Gently pull upward on the spray pump to lift away from the bottle.



- 2** Wash dust cap and spray pump in warm tap water.



- 3** Allow to dry completely.




When dry, place the spray pump and dust cap back on the bottle. **Re-prime the pump** before using Dymista® again.

IF PUMP IS BLOCKED

IF SPRAY PUMP IS BLOCKED: **X**

- Soak in warm water
- After pump is unblocked, rinse with cold water
- Allow to dry
- Replace dust cap
- **Do not try to unblock pump with a sharp object.** This can damage the spray pump and cause you to not get the right dose of medicine.



Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Dymista® Nasal Spray is a white suspension.

This medicine comes in an amber coloured glass bottle fitted with a spray pump, applicator and a protective cap. The 4 ml bottle contains 28 sprays. The 17 ml bottle contains 120 sprays. All pack sizes may not be marketed.

Ingredients

Dymista® Nasal Spray is a unique formulation containing the following active ingredients: azelastine hydrochloride and fluticasone propionate.

One spray contains 137 micrograms of azelastine hydrochloride and 50 micrograms of fluticasone propionate.

This medicine also contains the following inactive ingredients:

- glycerol
- microcrystalline cellulose
- carmellose sodium
- phenethyl alcohol
- disodium edetate
- benzalkonium chloride
- polysorbate 80
- purified water.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Limited
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 168 169

Date of Information

3 December 2018
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