

Package leaflet: Information for the user

Dymista Control **137 micrograms / 50 micrograms per Actuation** **Nasal Spray**

azelastine hydrochloride and fluticasone propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if your symptoms are not well controlled within 7 days.

What is in this leaflet:

1. What Dymista Control is and what it is used for
2. What you need to know before you use Dymista Control
3. How to use Dymista Control
4. Possible side effects
5. How to store Dymista Control
6. Contents of the pack and other information

1. What Dymista Control is and what it is used for

Dymista Control contains two active substances: 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 – thus reducing symptoms of hayfever.
- Fluticasone propionate belongs to a group of medicines called corticosteroids which reduce inflammation.

Dymista Control is used to relieve the symptoms of moderate to severe hayfever symptoms, if the use of either an antihistamine nasal spray or corticosteroid nasal spray alone has not provided relief.

Moderate to severe hayfever is an allergic reaction to substances such as pollen where sleep and/or daily living activities are affected (impairment of studies, work, leisure or sport) or symptoms are considered troublesome.

Dymista Control relieves the symptoms of hayfever, for example: runny nose, sneezing, itchy or blocked nose and red, itchy or watery eyes.

If you experience symptoms other than those associated with hayfever, speak to your doctor.

This product should only be used by adults aged 18 years and older.

2. What you need to know before you use Dymista Control

Do not use Dymista Control:

- If you are allergic to azelastine hydrochloride or fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Dymista Control if:

- You had a recent injury, operation or ulcers in your nose.
- You have a fever or an infection in your nose or sinuses. Infections of the nasal airways should be treated with antibacterial or antifungal medication. If you are given medication for an infection in your nose you can continue to use Dymista Control to treat your hayfever.
- You have tuberculosis or an untreated infection.
- You have a change in vision or a history of increased pressure in the eye, glaucoma and/or cataracts. If this applies to you, you will be closely monitored whilst using Dymista Control.
- You have recently been treated with injected steroids, or you have been taking oral steroids for a long time.
- You suffer from a severe liver disease. Your risk of suffering side effects affecting the whole body is increased.

In these cases, your doctor or pharmacist will decide whether you can use Dymista Control.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects affecting the whole body may occur due to the drug being absorbed in the body.

It is important that you take your dose as stated in section 3 below or as advised by your doctor or pharmacist. Treatment with higher than recommended doses of nasal corticosteroids may result in adrenal suppression, a condition that may produce weight loss, fatigue, muscle weakness, low blood sugar, salt cravings, joint pains, depression and darkening of the skin. If this happens, your doctor may recommend another medicine or during periods of stress, after serious injuries or before surgery.

Your doctor or pharmacist will advise you to use the lowest dose at which effective control of your hayfever symptoms is maintained.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are unsure whether the above applies to you, talk to your doctor or pharmacist before using Dymista Control.

You must talk to a doctor if you do not feel better or if your symptoms are not well controlled within 7 days.

Children and adolescents

This medicine is not recommended for children and adolescents under 18 years of age.

Other medicines and Dymista Control

Tell your doctor or pharmacist, if you are taking, have recently taken or might take any of the following medicines:

- Corticosteroid medicines (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops)
- Medicines for HIV (e.g. ritonavir, cobicistat)
- Medicines for the treatment of fungal infections (e.g. ketoconazole)
- Medicines that may make you sleepy (e.g. diazepam, nitrazepam, zolpidem).

Some medicines may increase the effects of Dymista Control and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Dymista Control has minor influence on the ability to drive and use machines.

Very rarely, you may experience fatigue or dizziness due to the disease itself or when using Dymista Control. In these cases, do not drive or operate machinery.

Please be aware that drinking alcohol may enhance these effects.

Dymista Control contains benzalkonium chloride

This medicine contains 14 micrograms benzalkonium chloride in each spray, which is equivalent to 0.014 mg / 0.14 g. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. How to use Dymista Control

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in adults 18 years and older

- The recommended dose is one spray into each nostril in the morning and evening. Do not use more than 2 sprays in each nostril a day.

For therapeutic benefit whilst experiencing hayfever symptoms, using regularly in line with the instructions is essential.

Do not use continuously for more than **3 months** without consulting your doctor.

Stop taking Dymista Control and contact your doctor if your symptoms do not improve or are not well controlled within **7 days**.

Use only in the nose.

Contact with the eye should be avoided. Do not swallow.

Read the following instructions carefully and use only as directed.

Preparing the spray

Dymista Control is for use in your nose only. Do not spray Dymista Control in your eyes.

Before you use Dymista Control for the first time, you will need to prime the bottle.

5 STEPS TO USE Dymista Control

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



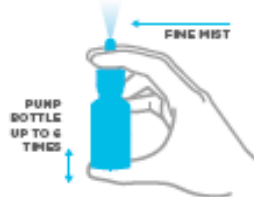
Remove the clear plastic dust cap from the spray pump tip of the bottle.



- 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.



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

- 3 CLEAR**
Blow your nose to clear nostrils.



Shake the bottle gently.



- 4 INSERT**
Close 1 nostril with a finger. Place spray pump tip just into your other nostril.



Tilt head forward slightly. Do not tilt head back. Open mouth.



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

- 5 SPRAY & BREATHE**
Keeping bottle upright and mouth open, pump once gently.



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

Repeat in other nostril.

REPEAT

Wipe off tip with clean tissue. Replace dust cap.



If you do not use your spray for 7 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**.

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.

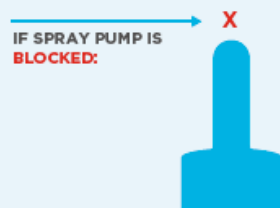


- 3 Allow to dry completely.



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

IF PUMP IS BLOCKED



- 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.

If you use more Dymista Control than you should

If you spray too much of this medicine into your nose you are unlikely to have any problems.

If you are worried or if you have used doses higher than recommended over a long period, contact your doctor.

If anyone, especially a child, accidentally swallows Dymista Control, contact your doctor or nearest hospital casualty department as soon as possible.

If you forget to use Dymista Control

Use your nasal spray as soon as you remember, then take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Seek immediate medical help if you have any of the following symptoms:

- **Swelling of face, lips, tongue or throat which may cause difficulty in swallowing/breathing and a sudden onset of skin rash.** This could be signs of a severe allergic reaction. *Please note: This is very rare.*

Other side effects

Very common side effects (may affect more than 1 in 10 people):

- Nosebleed.

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

- Headache.
- A bitter taste in your mouth, especially if you tilt your head backwards when you are using the nasal spray. This should go away if you have a soft drink a few minutes after using this medicine.
- Unpleasant smell.

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

- Slight irritation of the inside of the nose. This can cause mild stinging, itching.
- Sneezing.
- Nasal dryness, cough, dry throat or throat irritation.

Rare side effects (may affect up to 1 in 1,000 people):

- Dry mouth.

Very rare side effects (These may affect up to 1 in 10,000 people):

- Dizziness or drowsiness.
- Cataract, glaucoma or increased pressure in your eye where you may have a loss of vision and/or red and painful eyes. These side effects have been reported following prolonged treatment with fluticasone propionate - containing nasal sprays.
- Damage of the skin and mucous membrane in the nose.
- Feeling sick, weary, exhausted or weak.
- Rash, itchy skin or red, raised itchy bumps.
- Bronchospasm (the narrowing of the airways in the lungs).

Side effects with unknown frequency (frequency cannot be estimated from the available data):

- Blurred vision.
- Sores in the nose.

Systemic side effects (side effects concerning the whole body) may occur when this medicine is used at high doses for a long time. These effects are much less likely to occur if you use a corticosteroid

nasal spray than if you take corticosteroids by mouth. These effects may vary in individual patients and between different corticosteroid preparations (see section 2).

Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time.

In rare cases a reduction of the bone density (osteoporosis) was observed, if nasal corticosteroids were administered long-term.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dymista Control

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and the outer carton after "EXP". The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Shelf life after first opening: Dispose of any unused medicine 6 months after you first open the nasal spray.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dymista Control contains

- The active substances are: azelastine hydrochloride and fluticasone propionate. Each g of suspension contains 1000 micrograms azelastine hydrochloride and 365 micrograms fluticasone propionate. Each actuation (0.14 g) delivers 137 micrograms azelastine hydrochloride (= 125 micrograms azelastine) and 50 micrograms fluticasone propionate.
- The other ingredients are: disodium edetate, glycerol, microcrystalline cellulose, carmellose sodium, polysorbate 80, benzalkonium chloride, phenylethyl alcohol and purified water.

What Dymista Control looks like and contents of the pack

Dymista Control is a white, homogenous suspension.

Dymista Control comes in an amber-coloured glass bottle fitted with a spray pump, applicator and a protective cap.

Dymista Control comes in a 25 ml bottle containing 23 g nasal spray, suspension (at least 120 sprays).

Dymista Control is presented in packs containing 1 bottle with 23 g nasal spray, suspension.

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