**Package leaflet: Information for the patient**

**Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray, Suspension**

Azelastine hydrochloride/fluticasone propionate

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

**What is in this leaflet:**


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

Dymista 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 allergic rhinitis.
- Fluticasone propionate belongs to a group of medicines called corticosteroids which reduces inflammation.

Dymista is used to relieve the symptoms of moderate to severe seasonal and perennial allergic rhinitis if the use of either intranasal antihistamine or corticosteroid alone is not considered sufficient.

Seasonal and perennial allergic rhinitis are allergic reactions to substances such as pollen (hayfever), house mites, moulds, dust or pets.

Dymista relieves the symptoms of allergies, for example: runny nose, post nasal drip, sneezing and itchy or blocked nose.

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

**Do not use Dymista:**
- 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 if:
- You had a recent operation on your nose.

- You have an infection in your nose. 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 to treat your allergies.
- You have tuberculosis or an untreated infection.
- You have a change in vision or a history of increased ocular pressure, glaucoma and/or cataracts. If this applies to you, you will be closely monitored whilst using Dymista.
- You suffer from impaired adrenal function. Care must be taken when transferring from systemic steroid treatment to Dymista.
- You suffer from a severe liver disease. Your risk of suffering from systemic side effects is increased.

In these cases your doctor will decide whether you can use Dymista.

It is important that you take your dose as stated in section 3 below or as advised by your doctor. 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 during periods of stress or elective surgery.

To avoid adrenal suppression your doctor will advise you to take the lowest dose at which effective control of your symptoms of rhinitis is maintained.

Taking nasal corticosteroids (such as Dymista) may when taken for a long time cause children and adolescents to grow more slowly. The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose.

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.

**Children**
This medicine is not recommended for children under 12 years.

**Other medicines and Dymista**
Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

**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 Dymista.

**Driving and using machines**
Dymista 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. In these cases, do not drive or operate machinery. Please be aware that drinking alcohol may enhance these effects.

**Dymista 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

Always use Dymista exactly as your doctor has told you. Check with your doctor or pharmacist, if you are not sure.

It is essential to use Dymista regularly to gain the full therapeutic benefit.

Contact with the eyes should be avoided.

**Adults and adolescents (12 years and above)**

- The recommended dose is one spray into each nostril in the morning and evening.

**Use in children under 12 years**

- This medicine is not recommended for children under 12 years.

**Use in renal and hepatic impairment**

- There are no data in patients with renal and hepatic impairment.

**Method of administration**

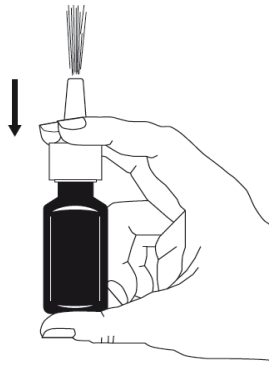
For nasal use.
Read the following instructions carefully and use only as directed.

**INSTRUCTION FOR USE**
**Preparing the spray**
1. Shake the bottle gently for 5 seconds by tilting it upwards and downwards 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 by squirting it into the air.
3. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
4. Press down and release the pump 6 times until a fine mist appears (see figure 2).
5. Now your pump is primed and ready to use.

Figure 2



6. If the nasal spray has not been used for more than 7 days, you will need to re-prime the pump once by pressing down and releasing the pump.

**Using the spray**

1. Shake the bottle gently for 5 seconds by tilting it upwards and downwards and then remove the protective cap (see figure 1).
2. Blow your nose to clear your nostrils.
3. Keep your head tilted downwards towards your toes. Do not tilt head backwards.
4. Hold the bottle upright and carefully insert the spray tip into one nostril.
5. Close other nostril with your finger, rapidly press down once and sniff gently at the same time (see figure 3).
6. Breathe out through your mouth.

Figure 3

7. Repeat in your other nostril.
8. 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

9. After each use wipe the spray tip with a clean tissue or cloth and then replace the protective cap.
10. Do not prick the nozzle in case spray is not obtained. Clean the actuator with water.

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

**Duration of treatment**
Dymista is suitable for long-term use. The duration of treatment should correspond to the period of experiencing allergy symptoms.

**If you use more Dymista 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 drinks Dymista, contact your doctor or nearest hospital casualty department as soon as possible.

**If you forget to use Dymista**
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.

**If you stop using Dymista**
Do not stop using Dymista without asking your doctor, because this puts the success of the treatment at risk.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

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

**Very common side effects (These may affect more than 1 in 10 people):**
- Nosebleed

**Common side effects (These 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 (These may affect up to 1 in 100 people):**
- Slight irritation of the inside of the nose. This can cause mild stinging, itching or sneezing.
- Nasal dryness, cough, dry throat or throat irritation

**Rare side effects (These 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 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)

**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.***

**Side effects with unknown frequency (frequency cannot be estimated from 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 children and adolescents this side effect can cause them to grow more slowly than others.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below).
By reporting side effects, you can help provide more information on the safety of this medicine.
Ireland: HPRA Pharmacovigilance. website: www.hpra.ie.
Malta: ADR Reporting. website: www.medicinesauthority.gov.mt/adrportal.

## 5. How to store Dymista

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 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 looks like and contents of the pack**
Dymista is a white, homogenous suspension.
Dymista comes in an amber coloured glass bottle fitted with a spray pump, applicator and a protective cap.
The 10 ml bottle contains 6.4 g nasal spray, suspension (at least 28 actuations). The 25 ml bottle contains 23 g nasal spray, suspension (at least 120 actuations).
Dymista is presented in:
Packs containing 1 bottle with 6.4 g nasal spray, suspension
Packs containing 1 bottle with 23 g nasal spray, suspension
Multipacks comprising 10 bottles, each containing 6.4 g nasal spray, suspension
Multipacks comprising 3 bottles, each containing 23 g nasal spray, suspension.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Viatris Healthcare Limited,
Damastown Industrial Park,
Mulhuddart Dublin 15,
DUBLIN Ireland

**Manufacturer**
MEDA Pharma GmbH & Co. KG
Benzstraße 1
D-61352 Bad Homburg
Germany

Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

| | | | |
|---|---|---|---|
| Austria | Dymista Nasenspray | Latvia | Dymista 137 mikrogrami/50 mikrogrami devā deguna aerosols, suspensija |
| Bulgaria | Dymista | Liechtenstein | Dymista Nasenspray |
| Cyprus | Dymista Ρινικό εκνέφωμα | Lithuania | Dymista 137 mikrogramai/50 mikrogramų / dozėje nosies purškalas (suspensija) |
| Czech Republic | Dymistin 137 mikrogramů / 50 mikrogramů, nosní sprej, suspenze | Luxembourg | Dymista Neusspray / Suspension pour pulvérisation nasale / Nasenspray |
| Denmark | Dymista | Malta | Dymista Nasal Spray |
| Estonia | Dymista | Norway | Dymista nesespray |
| Finland | Dymista nenäsumute | Poland | Dymista |
| France | Dymistalin Suspension pour pulvérisation nasale | Portugal | Dymista Spray nasal |
| Germany | Dymista Nasenspray 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension | Romania | Dymista 137 microgram / 50 microgram /doza spray nazal suspensie |
| Greece | Dymista Ρινικό εκνέφωμα | Slovak Republic | Dymista nosová aerodisperzia |

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|---|---|---|---|
| Hungary | Dymista Szuszpenziós orrspray | Slovenia | Dymista 137 mikrogramov / 50 mikrogramov na vpih pršilo za nos, suspenzija |
| Iceland | Dymista Nefúði | Spain | Dymista suspensión pulverización nasal |
| Ireland | Dymista, 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension | Sweden | Dymista Näs别spray, suspension (1mg/g; 0.365 mg/g) |
| Italy | Dymista | United Kingdom (Northern Ireland)_ | Dymista Nasal Spray |

This leaflet was last revised in June 2023