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 must be 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
2. What you need to know before you use Dymista
3. How to use Dymista
4. Possible side effects
5. How to store Dymista
6. Contents of the pack and other information

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 an intranasal antihistamine or corticosteroid is not considered sufficient. Seasonal and perennial allergic rhinitis are allergic reactions to substances such as pollen (hay fever), house dust 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).
- If 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 take when 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.

Older medicines and Dymista
Tell your doctor or pharmacist, if you are taking, have recently taken or might take any other medicines, including over-the-counter 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 which may cause irritation of the nasal mucosa and bronchoospasm. 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.

Instruction for use
Figure 1
1. Shake the bottle gently for 5 seconds by tilting it upwards and downwards and then remove the protective cap (see figure 1).
2. The first time the nasal spray is used, you must prime the pump by squeezing 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).

Figure 2
1. Blow your nose to clear your nostrils.
2. The first time the nasal spray is used, you must prime the pump by squeezing it into the air.
3. Keep your head tilted downwards towards your toes. Do not tilt head backwards.
4. Squeeze 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).

Figure 3
6. Breathe out through your mouth.
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 the 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.

Method of administration
For nasal use.

Read the following instructions carefully and use only as directed.

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).
2. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle.
3. Press down and release the pump 6 times until a fine mist appears (see figure 2).

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 down towards your toes. Do not tilt head backwards.
4. Squeeze 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).

Suspension
Dymista® 137 micrograms / 50 micrograms per actuation, Nasal Spray, Suspension azelastine hydrochloride/fluticasone propionate

- 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.
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 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):
-干涩感
-鼻腔干热
-头昏
-流鼻涕

Common side effects (These may affect up to 1 in 10 people):
- 鼻塞
- 鼻腔干热
- 咳嗽
- 鼻腔干热

Uncommon side effects (These may affect up to 1 in 100 people):
- 肌肉疼痛
- 鼻腔干热
- 鼻塞
- 鼻腔干热

Rare side effects (These may affect up to 1 in 1000 people):
- 干咳
- 流鼻涕

Very rare side effects (These may affect up to 1 in 10,000 people):
- 晕厥
- 呼吸困难
- 食欲不振
- 疲劳

Side effects with unknown frequency (frequency cannot be estimated from available data):
- 视力模糊
- 鼻腔干燥

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 include any possible side effects not listed in this leaflet. You can also include any possible side effects not listed in this leaflet.

If you get any side effects, talk to your doctor, pharmacist or nurse.

5. How to store Dymista

Store the 25 ml bottle contains 23 g nasal spray, suspension (at least 120 actuations). Packs containing 1 bottle with 23 g nasal spray suspension.

Parallel Product Authorisation Holder and Manufacturer

Parus Product Authorisation Holder: Procurled from within the EU by the Parallel Product Authorisation holder: Merit Pharmaceuticals Ltd., Unit C4/C3 Metropoint Business Park, Kettles Lane, Swords, Co. Dublin, K67 RH62, Ireland.

Repackaged by Suerte Pharma Ltd., 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS UK.

Distributed by Merit Pharmaceuticals Ltd., Swords, County Dublin.

Manufacturer: MEDA Pharma GmbH & Co. KG, Branstr. 1, 61352 Bad Homburg, Germany.

PPA239880/18/001

This medicinal product is authorised in the Member States of the EEA under the following names:

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