DYMISTA CONTROL LONG FORM ESSENTIAL INFORMATION

Please refer to the Summary of product characteristics (SmPC) for full information before recommending this product.

Dymista Control 137 micrograms / 50 micrograms per Actuation Nasal Spray. Contains azelastine hydrochloride and fluticasone propionate.

Indication: Relief of symptoms of moderate to severe seasonal allergic rhinitis in adults if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.

Dosage and method of use: 18 years of age or over**:** The recommended dose is one actuation in each nostril twice daily (morning and evening). The maximum daily dose should not exceed 2 sprays in each nostril per day. Dymista Control Nasal Spray should not be used in children and adolescents under 18 years of age. Dymista Control Nasal Spray is for nasal use only.

Contra-indications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: Treatment should be stopped, or the advice of a doctor sought if an improvement is not seen within 7 days. The advice of a doctor or pharmacist should also be sought if symptoms have improved but are not adequately controlled within 7 days. This medicine should not be used for more than 3 months continuously without consulting a doctor.

Medical advice should be sought before using this medicine in the case of:

- concomitant use of other corticosteroid products, such as tablets, creams, ointments, asthma medications, similar nasal sprays, or eye/nose drops.
- fever or an infection in the nasal passages or sinuses.
- recent injury or surgery to the nose, or problems with ulceration in the nose.

Clinically significant drug interactions in patients receiving fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side-effects.

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression, or aggression.

Dymista Control Nasal Spray undergoes extensive first-pass metabolism, therefore the systemic exposure of intranasal fluticasone propionate in patients with severe liver disease is likely to be increased. This may result in a higher frequency of systemic adverse events. Caution is advised in these patients.

Treatment with higher than recommended doses of nasal corticosteroids may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used,

then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

In general, the dose of intranasal fluticasone formulations should be reduced to the lowest dose at which effective control of the symptoms of rhinitis is maintained. Higher doses than the recommended one have not been tested for Dymista Control. As with all intranasal corticosteroids, the total systemic burden of corticosteroids should be considered whenever other forms of corticosteroid treatment are prescribed concurrently.

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma, or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Close monitoring is warranted in patients with a change in vision or with a history of increased ocular pressure, glaucoma and/or cataracts.

If there is any reason to believe that adrenal function is impaired, care must be taken when transferring patients from systemic steroid treatment to Dymista Control Nasal Spray.

In patients who have tuberculosis, any type of untreated infection, or have had a recent surgical operation or injury to the nose or mouth, the possible benefits of the treatment with Dymista Control Nasal Spray should be weighed against possible risk. Infections of the nasal airways should be treated with antibacterial or antimycotical therapy, but do not constitute a specific contraindication to treatment with Dymista Control Nasal Spray. Dymista Control Nasal Spray contains benzalkonium chloride. Long term use may cause oedema of the nasal mucosa.

Side-effects: Very Common (≥1/10): Epistaxis. Common (≥1/100 and <1/10): Headache, dysgeusia (unpleasant taste), unpleasant smell. Uncommon (≥1/1,000 and <1/100): Nasal discomfort (including nasal irritation, stinging, itching), sneezing, nasal dryness, cough, dry throat, throat irritation. Rare (≥1/10,000 and <1/1000): Dry mouth. Very rare (<1/10,000): Hypersensitivity including anaphylactic reactions, angioedema (oedema of the face or tongue and skin rash), bronchospasm, dizziness, somnolence, glaucoma, increased intraocular pressure, cataract, nasal septal perforation, mucosal erosion, nausea, rash, pruritus, urticaria, fatigue, weakness. Side effects where the frequency cannot be estimated from available data: blurred vision, nasal ulcers. Systemic effects of some nasal corticosteroids may occur, particularly when administered at high doses for prolonged periods. In rare cases osteoporosis was observed if nasal glucocorticoids were administered long-term.

Product licence number: PL 46302/0094 **Name and address of the product licence holder:** Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom. **Supply classification:** P. **Cost:** £13.72 (Trade price) **Document number:** UK-DTC-2024-00044. **Date last revised**: December 2024

Please continue to report suspected adverse drug reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report adverse drug reactions online via the Yellow Card website: https://yellowcard.mhra.gov.uk/ or search for MHRA. Yellow Card in the Google Play or Apple App Store. Alternatively, you can report via some clinical IT systems(EMIS/SystmOne/Vision/MiDatabank) or by calling the Commission on Human Medicines(CHM)

free phone line: 0800-731-6789. Adverse reactions/events should also be reported to MAH at e-mail address: pv.uk@viatris.com