Dymista® Nasal Spray, Suspension (azelastine hydrochloride/ fluticasone propionate) Prescribing Information

Presentation: Nasal spray suspension. Each gram of suspension contains 1000 micrograms of azelastine hydrochloride and 365 micrograms of fluticasone propionate. **Indications:** Relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis if treatment with intranasal antihistamine or glucocorticoid alone is not considered sufficient. **Dosage and administration:** Adults and adolescents (12 years and older): One actuation into each nostril twice daily. Children below 12 years: not recommended as safety and efficacy has not been established in this age group. **Contra-indications:** Hypersensitivity to azelastine hydrochloride or fluticasone propionate or any of the other ingredients in this medicine. **Warnings and precautions:** Avoid concomitant use with ritonavir. Systemic effects of nasal corticosteroids may occur. Systemic exposure in severe liver disease may be increased. Dymista® may result in clinically significant adrenal suppression. Patients may experience blurred vision or other visual disturbances. Monitor patients who experience changes in vision or have a history of ocular pressure, glaucoma and/or cataract. If adrenal function is impaired, take care when changing medication to Dymista®. In patients with infections, recent surgery or injury to nose or mouth, weigh benefits against risks of use. Contains benzalkonium chloride. Long term use may cause oedema of the nasal mucosa. Experience of use in pregnancy and lactation is limited. Dymista® should only be used if the potential benefit justifies the potential risk. Dymista® has minor influence on ability to drive and use machines. **Undesirable Effects:** Epistaxis, headache, dysgeusia, unpleasant smell, hypersensitivity reactions including anaphylactic reactions, angioedema, bronchospasm, glaucoma, increased intraocular pressure, cataract, blurred vision, septal perforation, nasal irritation, nasal ulcers, throat irritation, nausea, dizziness, sleepiness, fatigue, rash, dry mouth, growth retardation may be possible in adolescents receiving prolonged treatment and growth should be monitored regularly. Consult the Summary of Product Characteristics for other side effects. **Package Quantities and Basic Price (UK):** £14.80 for 23g bottle. Each spray (0.14 g) contains 137 mcg of azelastine hydrochloride and 50 mcg of fluticasone propionate. **Legal category:** POM. **Product Licence Holder:** Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom. Tel 0845 460 0000. **Marketing Authorisation Number:** PL 46302/0162. **Date of preparation of prescribing information:** February 2021
DYM-2021-0153

Adverse Drug Reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should be reported to UK Pharmacovigilance, Mylan, Building 4, Trident Place, Hatfield Business Park, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, on phone no. +44 (0) 800 121 8267, Email: pv.uk@viatris.com