Formulary decision guide: Dymista® Nasal Spray (azelastine hydrochloride/fluticasone propionate)

Dymista® Nasal Spray (azelastine hydrochloride/fluticasone propionate)

Indication

• Dymista is a combination nasal spray indicated for the relief of symptoms of moderate to severe seasonal and perennial allergic rhinitis, in adults and adolescents, aged 12 years and older, if monotherapy with either intranasal antihistamine or glucocorticoid is not considered sufficient.

Formulation

• Dymista contains two active ingredients, azelastine hydrochloride and fluticasone propionate
• The vehicle spray formulation is not available in any other commercially available medication and has the following features when compared with either ingredient alone: greater spray volume; finer droplet size distribution; lower viscosity; and wider spray angle.

Dosage and administration

• Each spray (0.14 g) contains 137 mcg of azelastine hydrochloride and 50 mcg of fluticasone propionate
• Adults and adolescents (12 years and older):2
  – one actuation into each nostril twice daily (morning and evening)
  – Dymista nasal spray is suitable for long-term use
  – duration of treatment should correspond to the period of allergenic exposure.

Guidance

• The 2017 BSACI guideline recommends a combination of topical AH and INS for use as part of a stepwise pharmacological treatment algorithm in patients with rhinitis when symptoms remain uncontrolled on AH or INS.

Efficacy

• Evidence to support Dymista efficacy comes from meta-analysis and double-blind placebo-controlled clinical trials in more than 4000 patients aged 12 years and older with seasonal and perennial rhinitis
• According to trial data, Dymista:
  – led to greater symptom relief than using either azelastine or fluticasone propionate alone in SAR
  – significantly improved all symptoms of AR with onset of action by 30 minutes
  – led to clinical improvement of symptoms days earlier than with fluticasone propionate or azelastine alone
  – achieved significantly greater improvement in ocular symptoms of allergy than fluticasone propionate alone
  – demonstrated efficacy over fluticasone propionate in perennial AR.

Place in therapy

• With the availability of effective combination therapies, such as Dymista, an intranasal formulation in a single device, the majority of AR symptoms can be treated in the primary care setting
• Challenges in the management of patients with rhinitis include:
  – the high proportion of individuals with moderate or severe disease, or persistent disease, who experience breakthrough symptoms while on therapy, resulting in dissatisfaction and non-compliance with their medication
  – patients with SAR prefer treatments that are more efficacious and fast acting
  – patients with AR are currently on multiple therapies, and for the majority of patients this achieves no additional benefit in symptom relief
  – patients with AR visit the GP numerous times in an attempt to achieve symptom control.

Cost of INS and topical AH treatment

<table>
<thead>
<tr>
<th>Commonly used nasal sprays*</th>
<th>Dymista® (azelastine hydrochloride/fluticasone propionate)</th>
<th>£14.80 (120 doses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avamys® (fluticasone furoate)</td>
<td>£6.44 (120 doses)</td>
<td>£2.63 (200 doses)</td>
</tr>
<tr>
<td>Beconase® (beclometasone dipropionate monohydrate)</td>
<td>£11.01 (150 doses)</td>
<td>Nasonex® (mometasone furoate)</td>
</tr>
<tr>
<td>Flixonase® (fluticasone propionate)</td>
<td>£2.63 (200 doses)</td>
<td></td>
</tr>
<tr>
<td>Rhinolast® (azelastine hydrochloride)</td>
<td>£10.50 (~150 doses)</td>
<td></td>
</tr>
</tbody>
</table>

BSACI=British Society of Allergy and Clinical Immunology; AH=antihistamine; INS=intranasal steroid; SAR=seasonal allergic rhinitis; AR=allergic rhinitis; RCT=randomised controlled trial.

This formulary decision guide was developed from content provided by Mylan Ltd in a format developed by Guidelines in Practice.

Prescribing information can be found overleaf.
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Allergic rhinitis

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Guidelines in practice

• The guidance on a sequential treatment pathway for AR in primary care1 has the potential to limit the cost of providing AR management in the UK by avoiding unnecessary treatments and investigations, and avoiding the need for costly referrals to secondary care in the majority of AR cases.

Everyday use

• A study assessing the use, effectiveness, and safety of Dymista in routine clinical practice reported that its effectiveness observed in a real-world setting was better than in RCTs14
• Results in real-life14 and from RCTs have demonstrated complete and quick symptom reduction.8,14-16

Contraindications and precautions

• Hypersensitivity to the active substances or to any of the excipients listed
• See the Dymista Summary of Product Characteristics at www.medicines.org.uk/emc/medicine/27579 for special warnings and precautions for use.2

Side-effects

• Commonly, dysgeusia, a substance-specific unpleasant taste, may be experienced after administration (often due to incorrect method of application, namely tilting the head too far backwards during administration).2
• For further related safety information refer to the Summary of Product Characteristics.2

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. 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, sepal perforation, nasal irritation, 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: Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishops Stortford CM22 6PU. Tel 0845 460 0000. Marketing Authorisation Number: PL 15142/0258. Date of preparation of prescribing information: Nov 2017 UK/DYM/17/REF-28715

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Mylan by phone: 0800 121 8267 or by e-mail: ukpharmacovigilance@mylan.com

References
15. Prim Care Resp Med