ONSET OF ACTION WITHIN 5-10 MINUTES

Indications and clinical use:
DYMISTA® (azelastine hydrochloride/fluticasone propionate) is indicated for:
• the symptomatic treatment of moderate to severe seasonal allergic rhinitis (SAR) and associated ocular symptoms in adults, adolescents, and children aged 6 years and older for whom monotherapy with either antihistamines or intranasal corticosteroids is not considered sufficient.

Pediatrics (< 6 years of age):
DYMISTA is not recommended for use in children less than 6 years of age as safety and efficacy have not been established in this age group.

Contraindications:
• Untreated fungal, bacterial, or tuberculosis infections of the respiratory tract

Other relevant warnings and precautions:
• Systemic adverse effects
• Somnolence
• Local nasal adverse effects, inhibitory nasal wound healing, Candida infections, nasal ulceration and nasal septal perforation
• HPA axis adverse effects and effects on growth
• Suppression of immune system, avoid use in infections
• Ophthalmologic adverse effects
• Dysgeusia, epistaxis and headache
• Replacement of a systemic steroid
• Patients with hepatic dysfunction
• Concomitant use with strong CYP 3A4 inhibitors and cobicistat-containing products
• Avoid use with alcohol or other central nervous system depressants
• Psychological and behavioural effects
• Avoid use in patients with recent nasal ulcers, nasal surgery, or nasal trauma
• Pregnancy and nursing and risk of hypoadrenalism in newborns

For more information on The Dymista® Difference, visit www.dymista.ca

For more information:
Consult the Product Monograph at www.Mylan.ca for more information about conditions of clinical use, contraindications, warnings, precautions, adverse reactions, interactions and dosing. The Product Monograph is also available by calling 1-844-596-9526.

Dymista® is a registered trademark of MEDA AB, a Mylan company.

1. Bousquet J 2018, Onset of Action of the Fixed Combination JACI.
2. Dymista® Product Monograph, October 3, 2019.* Approximately 20.8 million treatment courses of DYMISTA have been dispensed worldwide since initial launch in the USA in Sep 2012. Data on file.
Onset of action in as little as 5 mins and ocular symptoms in 10 mins

**Dymista** is a fast-acting treatment for seasonal allergic rhinitis

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**Superior Nasal Symptom Control**

Reduction in total nasal symptom score (TNSS) in meta-analysis of three randomized trials

<table>
<thead>
<tr>
<th>Dymista vs Fluticasone Propionate</th>
<th>Dymista vs Azelastine</th>
<th>Dymista vs Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>12% more effective</td>
<td>30% more effective</td>
<td>90% more effective</td>
</tr>
</tbody>
</table>

The primary endpoint for the Reflective Total Nasal Symptom Score (rTNSS) was the change from baseline in the combined (daytime plus nighttime) 12-hour reflective total nasal symptom score (TNSS; maximum possible score of 30) over the 14-day study period vs. placebo, azelastine or fluticasone propionate alone.1

References:

1. Bousquet J 2018, Onset of Action of the Fixed Combination JACI.
3. Treatment Class with WHO Code ATC RO1AD58.

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**Superior Ocular Symptom Control**

Reduction in total ocular symptom score (TOSS) in meta-analysis of three randomized trials

<table>
<thead>
<tr>
<th>Dymista vs Fluticasone Propionate</th>
<th>Dymista vs Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>14% more effective</td>
<td>78% more effective</td>
</tr>
</tbody>
</table>

The secondary efficacy endpoint in the pivotal studies for the Reflective Total Ocular Symptom Score (rTOSS) was the change from baseline in combined (daytime plus nighttime) AM+PM rTOSS.1

References: