ONSET OF ACTION WITHIN 5-10 MINUTES[1,2]

DYMISTA – more than **20.8 million** patient-**treatments worldwide***

PrDymista®

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.

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.

DYM-2019-1079E - NO2019

Mylan
Better Health for a Better World™

PrDymista®

(Azelastine Hydrochloride/Fluticasone Propionate)137 mcg/50 mcg per metered spray

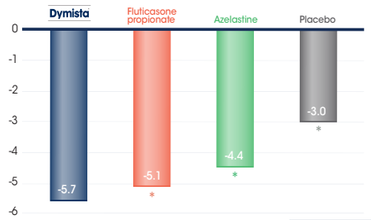
NOW WITH PEDIATRIC INDICATION

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

Superior Nasal Symptom Control[2]

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



Dymista vs. Fluticasone Propionate: **12%** more effective

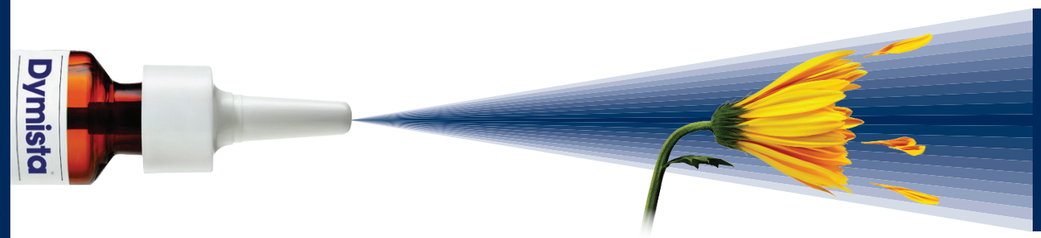
Dymista vs. Azelastine: **30%** more effective

Dymista vs. Placebo: **90%** more effective

TNSS

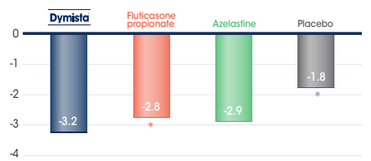
The primary end point for Reflective Total Nasal Symptom Score (rTNSS) was the change from baseline in the combined (daytime plus nighttime) 12-hour reflective total nasal symptom score (crTNSS: maximum possible score of 24) over the 14-day study period vs. placebo, azelastine or fluticasone propionate alone.[1]

*Effect of DYMISTA®, FP, and AZE on overall rTNSS (morning plus evening) in patients with moderate-to-severe SAR over a 14 day period. Data are expressed as means. AZE: Azelastine (137 mg per nostril bid); FP: fluticasone propionate (50 mg per nostril bid); DYMISTA®: (137/50 mg per nostril bid). DYMISTA® vs. FP = 0.001; DYMISTA® vs AZE < 0.001; DYMISTA® vs PLACEBO < 0.001



Superior Ocular Symptom Control[2]

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



Dymista vs. Fluticasone Propionate: **14%** more effective

Dymista vs. Placebo: **78%** more effective

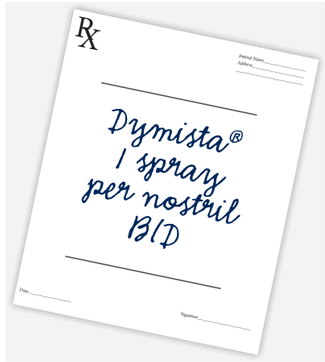
TOSS

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

*Effect of DYMISTA®, FP, and AZE on overall rTOSS (morning plus evening) in patients with moderate-to-severe SAR over a 14 day period. Data are expressed as means. AZE: Azelastine (137 mg per nostril bid); FP: fluticasone propionate (50 mg per nostril bid); DYMISTA®: (137/50 mg per nostril bid). DYMISTA® vs. FP = 0.022; DYMISTA® vs AZE not significant; DYMISTA® vs PLACEBO < 0.001

References: 1. Dymista® Product Monograph, October 3, 2019 . 2. Carr W, et al. J Allergy Clin Immunol. 2012 May;129(5):1282-9.

Dymista®



The Dymista® Difference

- The **only** nasal spray for seasonal allergic rhinitis that combines a corticosteroid with an antihistamine[3]
- Recommended by the **Canadian Allergic Rhinitis Guidelines**[4]
- Demonstrated similar efficacy profile for both adults and pediatric patients[5]
- Exhibits similar safety profile for both adults and children above 6 years of age[6]
- Same dosage for both Children (6 years of age and older) and Adults: spray 1's in each nostril twice a day (morning and evening).[2]

References:
1. Bousquet J 2018, Onset of Action of the Fixed Combination JACI.
2. Dymista® Product Monograph, October 3, 2019.
3. Treatment Class with WHO Code ATC R01AD58.
4. Small et al. Allergy Asthma Clin Immunol 2018.
5. Berger W et al. Allergy Asthma Proc 2018.
6. Berger W et al. Pediatr Allergy Immunol 2016.