Form Approved: OMB No. 0910-0001, Expiration Date: September 30, 2014; see OMB Statement on Page 3.

TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE

1. DATE SUBMITTED: 11/26/2012

2. LABEL REVIEW NO. (Biologics):

3. NDA/ANDA/AADA OR BLA/PLA/PMA
Number: 202-236
Single product ☒ Multiple products ☐
For multiple products, submit completed form and specimen of advertising/promotional materials to one application of choice, and attach separate sheet addressing items 3-5 for remainder of products. Refer to No. 3 on instruction sheet.

NOTE: Form 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81)

4. PROPRIETARY NAME	5. ESTABLISHED NAME
DYMISTA	azelastine hydrochloride and fluticasone propionate Prod. Code No.
6. PACKAGE INSERT DATE and ID NO. (Latest final printed labeling) IN-023A6-01 04/2012	7. MANUFACTURER NAME: MEDA Pharmaceuticals, MEDA Pharmaceuticals Inc. License No. (Biologics)

FDA/CBER USE ONLY

REVIEWED BY	DATE	RETURNED BY	DATE

8. **ADVERTISEMENT / PROMOTIONAL LABELING MATERIALS**

Please check only one: ☒ Professional ☐ Consumer

Material Type (use FDA codes) a.	Dissemination/ Publication Date b.	Applicant's Material ID Code and/or description c.	Previous review No. if applicable / date (PLA Submissions) d.	COMMENTS:
PSL	11/26/2012	DYM-12-0240: AAM Physician's Deck		.pdf submitted

DYM-12-0240
12 SVW 085 02
475 / 7814

Add Continuation Page

9. TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT	10. SIGNATURE OF RESPONSIBLE OFFICIAL
Kimberly Skopitz, RAC Manager, Regulatory Affairs	K. Skopitz
11. APPLICANT'S RETURN ADDRESS MEDA Pharmaceuticals Inc. 200 North Cobb Parkway, Bldg. 400, Suite 428 Marietta, GA 30062	12. RESPONSIBLE OFFICIAL'S a. PHONE NO. 770.916.3918 b. FAX NO. 678-718.3253
	13. FOR CBER PRODUCTS ONLY: *(Check one)* ☐ Part I/Draft ☐ Part II/Final

FORM FDA 2253 (9/11) PREVIOUS EDITION IS OBSOLETE. Page 1 of 3 PSC Publishing Services: (301) 443-6740 EF

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PSL	11/26/2012	DYM-12-0240: AAM Physician's Deck		.pdf submitted
				Add Continuation Page

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Kimberly Skopitz, RAC
Manager, Regulatory Affairs

10. SIGNATURE OF RESPONSIBLE OFFICIAL

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MEDA Pharmaceuticals Inc.
200 North Cobb Parkway, Bldg. 400, Suite 428
Marietta, GA 30062

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a. PHONE NO.
770.916.3918
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678-718.3253

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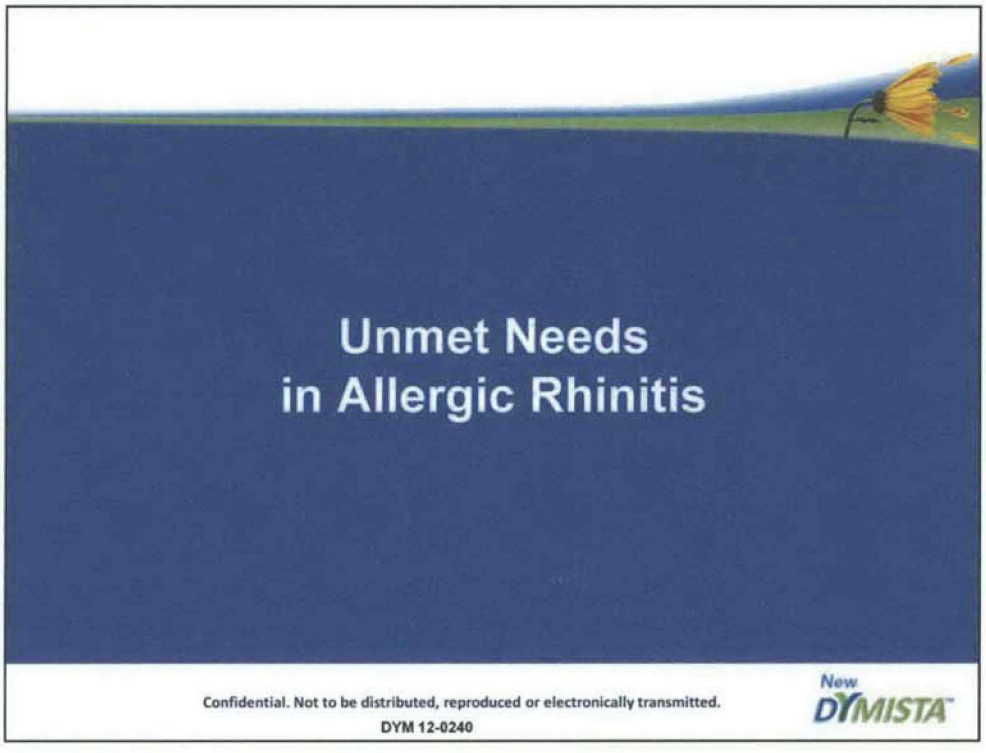
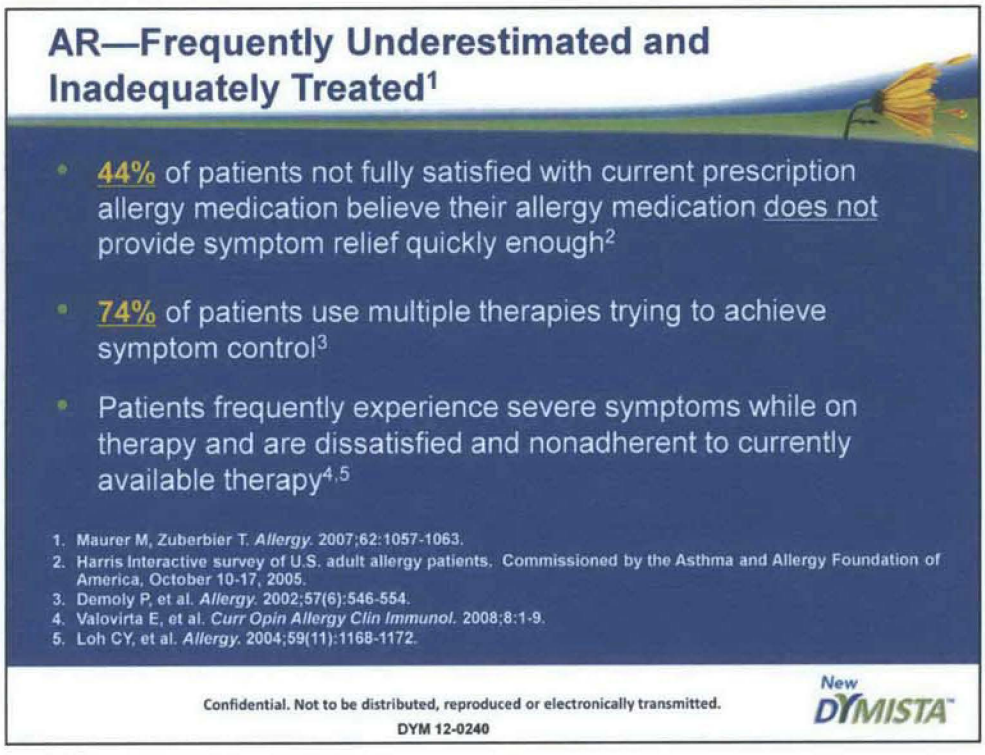
FORM FDA 2253 (9/11) PREVIOUS EDITION IS OBSOLETE. Page 1 of 3 PSC Publishing Services: (301) 443-6740 EF

Cover Slide

Customized by Speaker and Date per meeting



We are now going to look at the unmet medical needs and some patient perspectives on SAR collected from market research.



Many patients do not respond sufficiently to treatment
There are many patients who do not respond to therapy regardless of what is used to treat their symptoms.

There exists several challenges when treating our AR patients. They include:

1. Onset—**Patients want something that works fast**

2. Approximately 75% of patients suffering from AR use multiple therapies, increasing costs—**Patients want something that is effective**

3. Patient dissatisfaction with current treatment is a leading cause of increased costs and adherence—**Patients are still experiencing severe symptoms and are still seeking relief**

Survey Methodology:

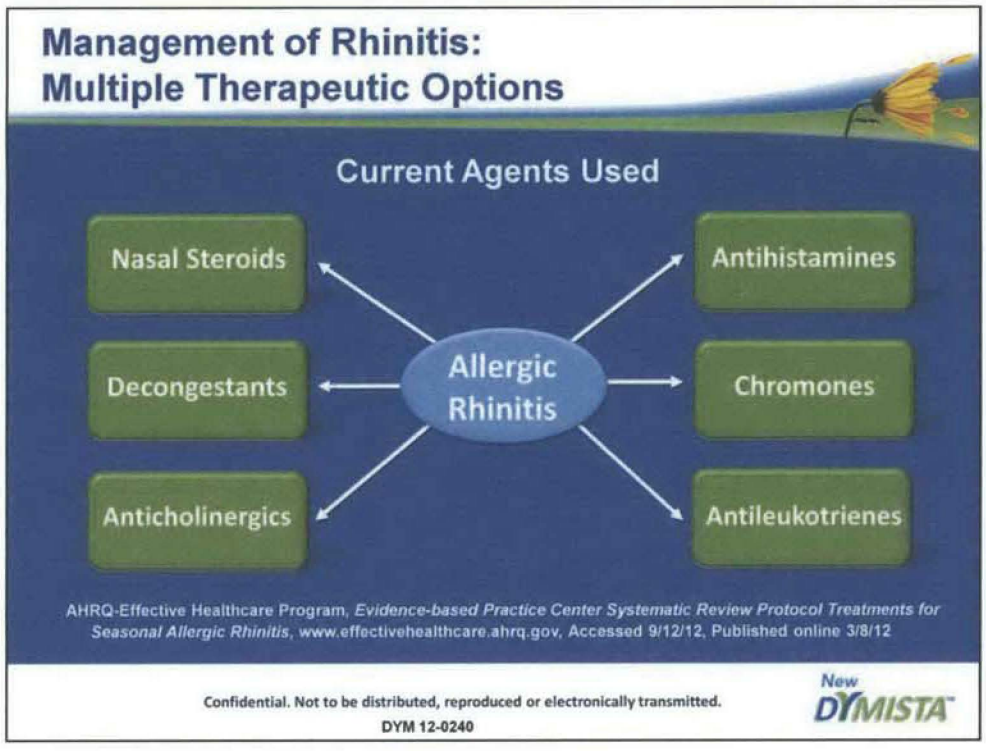
Harris Interactive conducted the online survey on behalf of AAFA from October 10-17, 2005, using its Chronic Illness Panel database. Total survey sampling includes a national sample of 1214 U.S. adults aged ≥18 years who have been diagnosed with seasonal allergies and are currently using prescription allergy medication to treat their allergies.

Data are weighted to be representative of adults aged ≥18 years who have been diagnosed with seasonal allergies and are currently using prescription allergy medication. Weighting was based on age within sex, education, race/ethnicity, region, income, and propensity to be online. In theory, with probability samples of this size, one can say with 95% certainty that the overall results have a sampling error of ±4.3 percentage points.

Sampling error for the sub-samples of patients who see a health care professional for seasonal

allergies (n=1194), patients who are not satisfied with their current prescription allergy medication (n=348), and patients who are not satisfied with the allergy care provided by their doctor or health care provider (n=242) is higher and varies. This online sample is not a probability sample.

We will now review some of the current therapeutic options to treat and manage SAR.

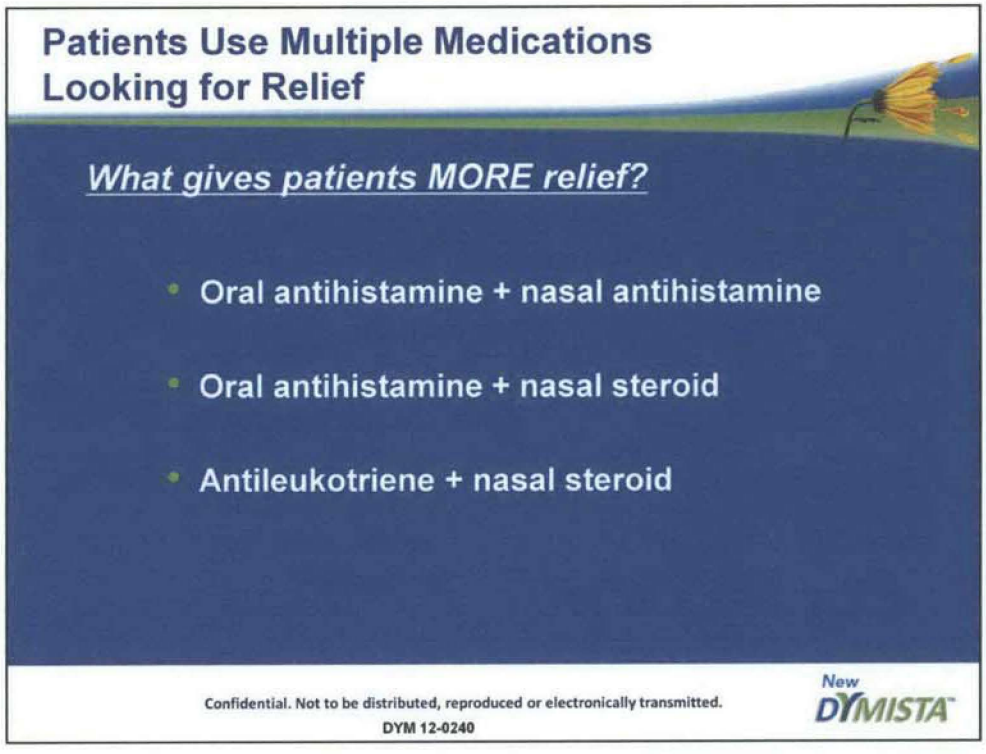


As noted previously, as many as 75% of patients use multiple therapies to achieve symptom control.

These are the major therapeutic classes of drugs used to treat SAR.

Speaker opens a discussion with the audience:

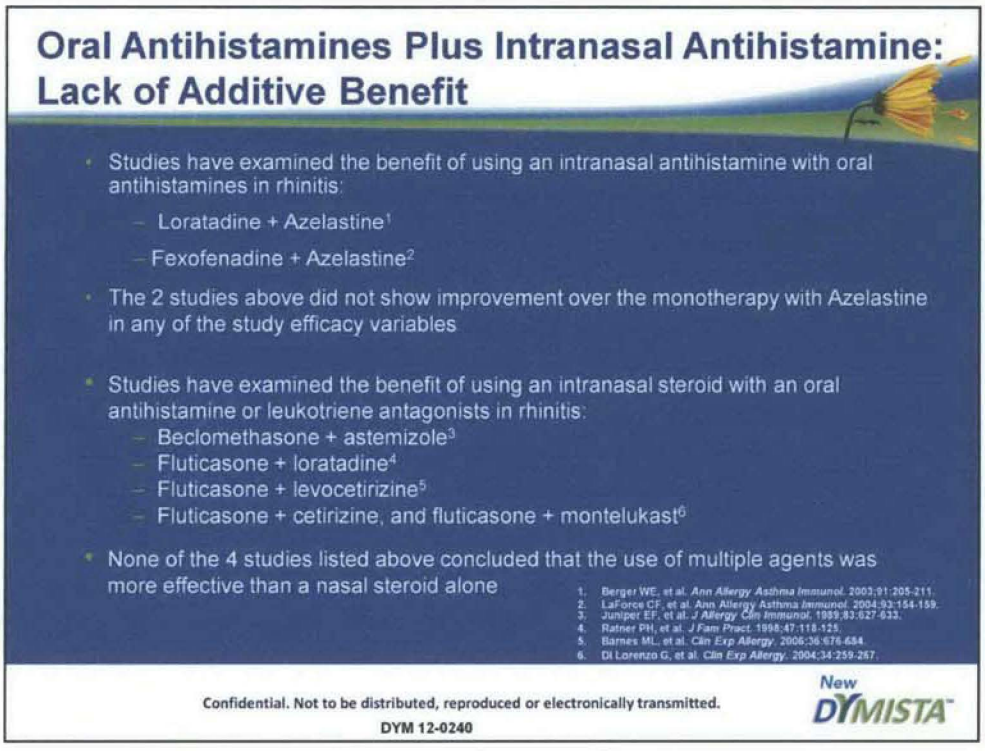
What are the agents you routinely employ? Why?



Can you provide some insight on your therapy selection?

Recall—Approximately 75% of patients suffering from AR use multiple therapies, leading to issues of increased costs.

How can we become more efficient in our management of SAR?



Speaker Note: Please briefly review the methodology, primary efficacy variable, and results with the audience. It is important for them to appreciate the lack of added benefits to polypharmacy for SAR patients.

Study Designs:

Berger

Two-week, multicenter, placebo-controlled, randomized, double-blind study in patients with moderate-to-severe symptoms of seasonal allergic rhinitis.

Following a 1-week, open-label lead-in period, during which the patients received loratadine 10 mg daily, those patients who met the symptom qualification criteria (<25% to 33% improvement taking loratadine) were randomized to treatment with (1) azelastine nasal spray 2 sprays per nostril twice daily plus placebo capsule once daily, (2) azelastine nasal spray 2 sprays per nostril twice daily plus loratadine 10 mg tablets once daily, (3) desloratadine 5 mg tablets once daily plus placebo nasal spray 2 sprays per nostril twice daily, or (4) placebo nasal spray 2 sprays per nostril twice daily plus placebo capsule once daily.

The primary efficacy variable was the change from baseline to day 14 in the total nasal symptom score, consisting of runny nose, sneezing, itchy nose, and nasal congestion symptom scores recorded twice daily (am and pm) in patient diary cards.

1. Berger WE, et al. *Ann Allergy Asthma Immunol.* 2003;91:205-211.

LaForce:

This was a multicenter, randomized, double blind, placebo controlled, 2-week study in patients with moderate-to-severe seasonal allergic rhinitis.

The study began with a 1-week, open-label lead-in period, during which patients received fexofenadine, 60 mg twice daily. Patients who improved less than 25% to 33% with fexofenadine were randomized to treatment with (1) azelastine nasal spray 2 sprays per nostril twice daily plus placebo capsules twice daily, (2) azelastine nasal spray 2 sprays per nostril twice daily plus fexofenadine 60 mg tablets twice daily, or (3) placebo nasal spray 2 sprays per nostril twice daily plus placebo capsules twice daily.

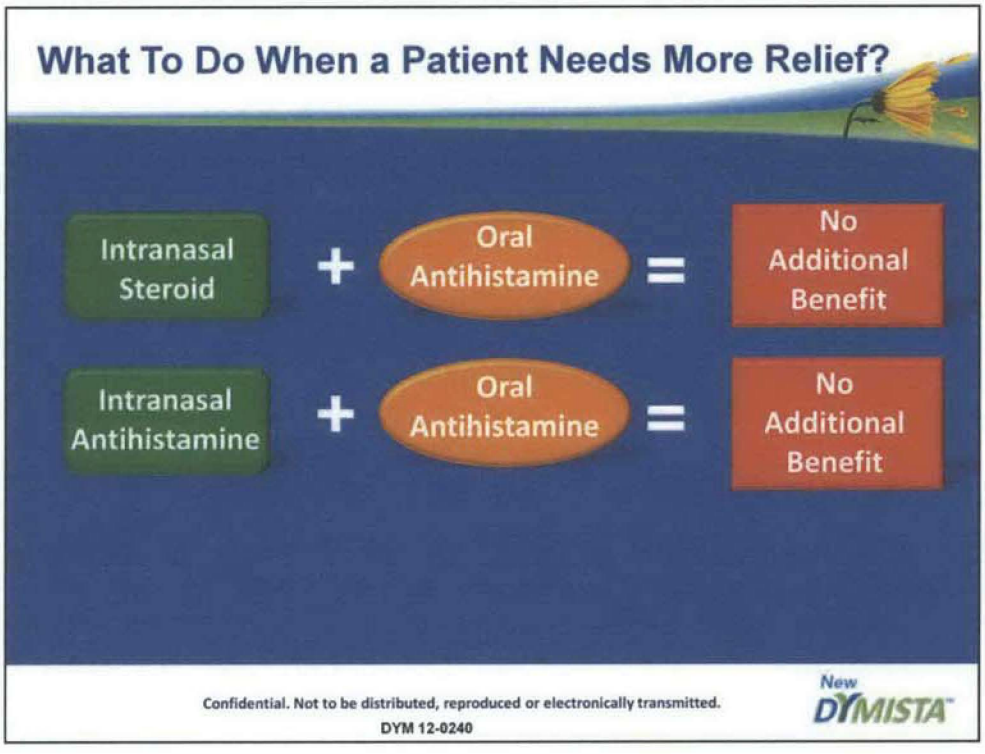
The primary efficacy variable was the change from baseline to day 14 in the total nasal symptom score (TNSS), consisting of runny nose, sneezing, itchy nose, and nasal congestion symptom scores.

2. LaForce CF, et al. *Ann Allergy Asthma Immunol.* 2004;93:154-159.

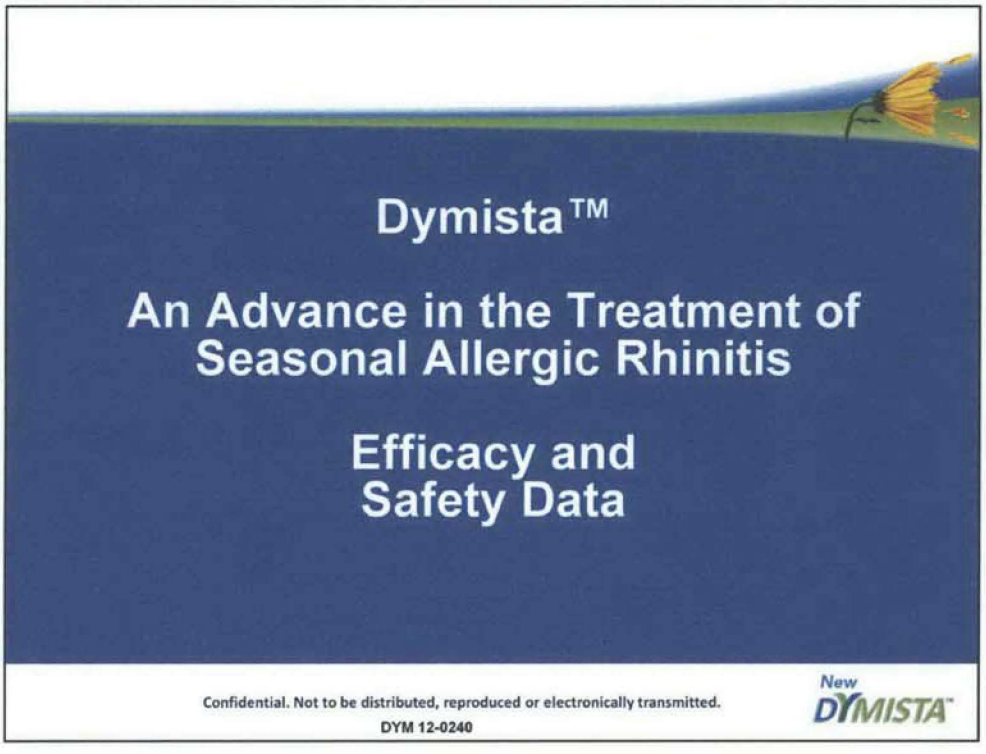
Speaker Note: Please initiate a discussion around these therapeutic choices for treating AR.

Have you experienced similar results?

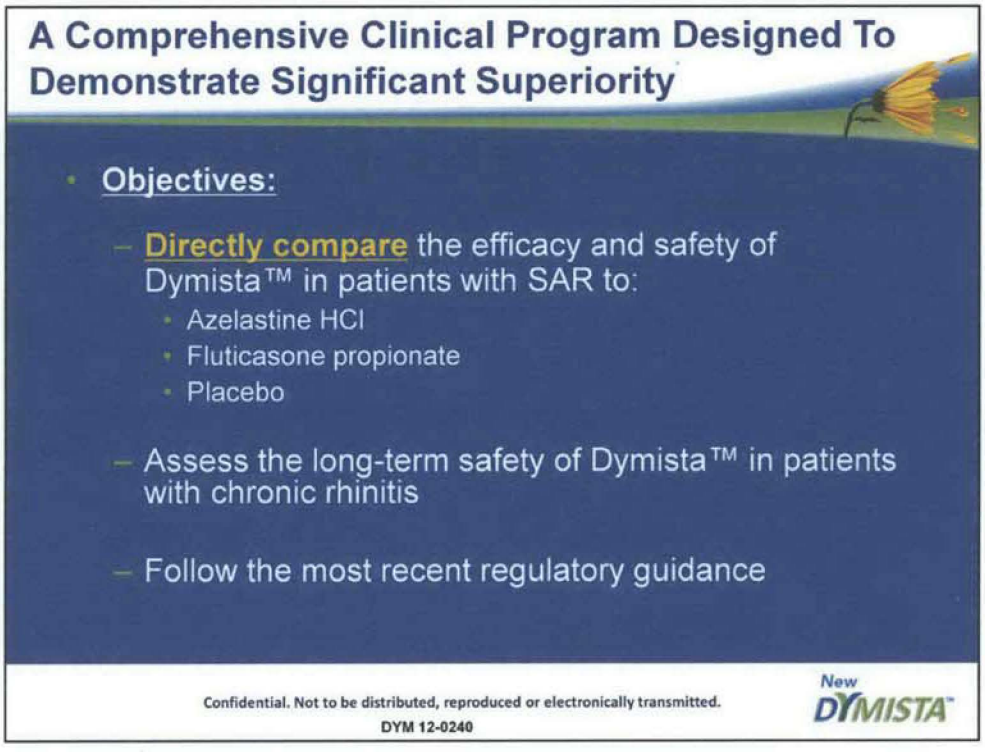
What agents do you think would provide a benefit to your patients? Why?



Is there a reason why we do this?



We will now review some of the clinical data on Dymista™.



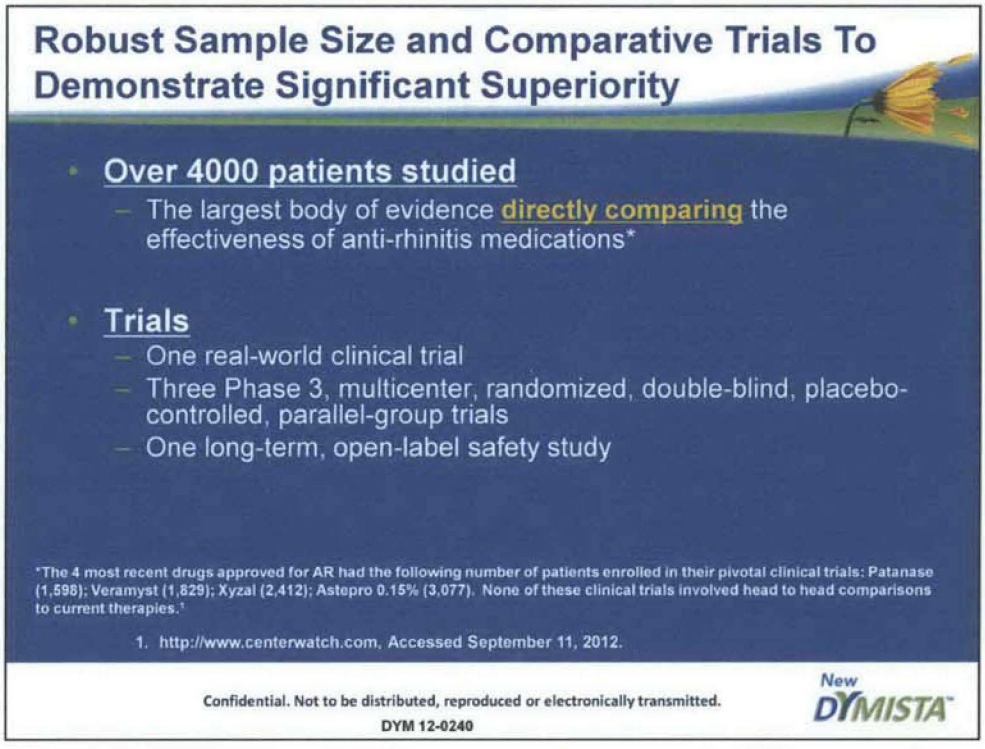
The 3 pivotal studies were designed to evaluate the efficacy and safety of Dymista™ to the 2 components of Dymista™, azelastine HCl and fluticasone propionate, in a **head-to-head comparison** for rapid and more complete symptom relief of SAR.

A long-term safety (12-month) study was conducted comparing Dymista™ to commercially available fluticasone propionate.

The FDA recently provided guidance to industry on the clinical trial design for new formulations of 2 or more drugs when each drug alone has activity and can be administered individually.[1]

Reference

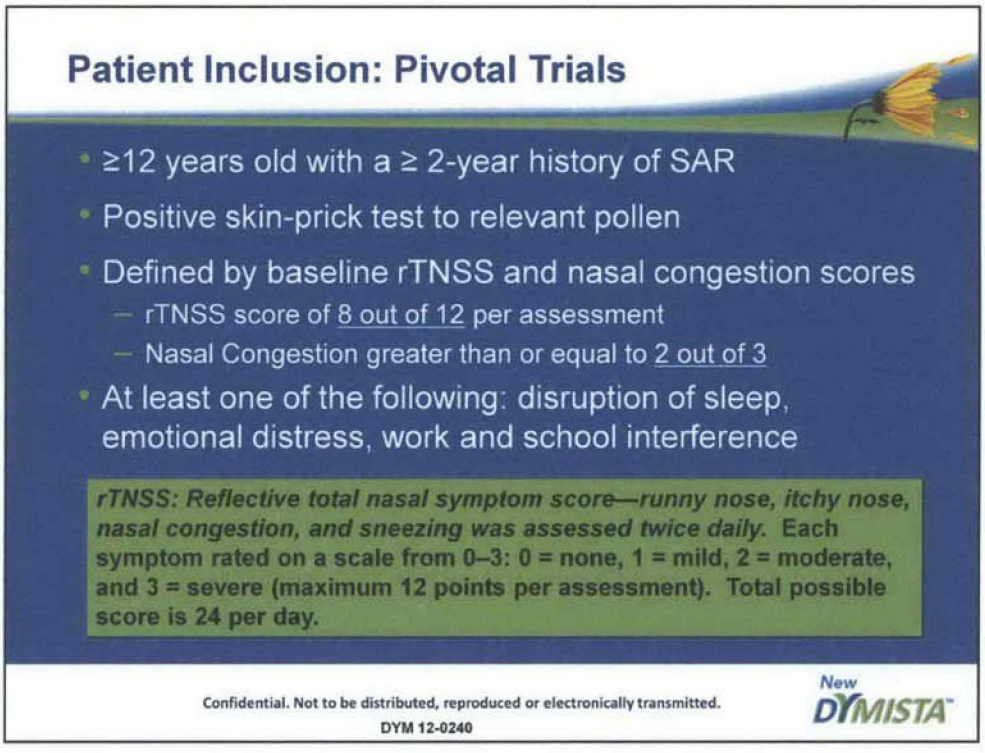
1. Center for Drug Evaluation and Research Guidance for Industry. Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combinations. December 2010.



The clinical development program for Dymista™ enrolled over 4000 patients, surpassing the clinical programs used for approval of the 4 most recently approved drugs for the treatment of AR.

***The 4 most recent drugs approved for AR had the following number of patients enrolled in their pivotal clinical trials: Patanase (1598); Veramyst (1829); Xyzal (2412); Astepro 0.15% (3077). None of these clinical trials involved head-to-head comparisons to current therapies.[1]**

Each of the clinical trials designed for Dymista™ involved active comparators. The next slide provides a listing of the comparators used in each trial. The total enrollment for the Dymista™ clinical trials totaled 4617 for all comparator trials.



The clinical trial program for Dymista™ Nasal Spray included four 2-week, randomized, double-blind, placebo- and active-controlled, parallel-group, clinical studies: MP4001, MP4002, MP4004, and MP4006. These studies share several characteristics:

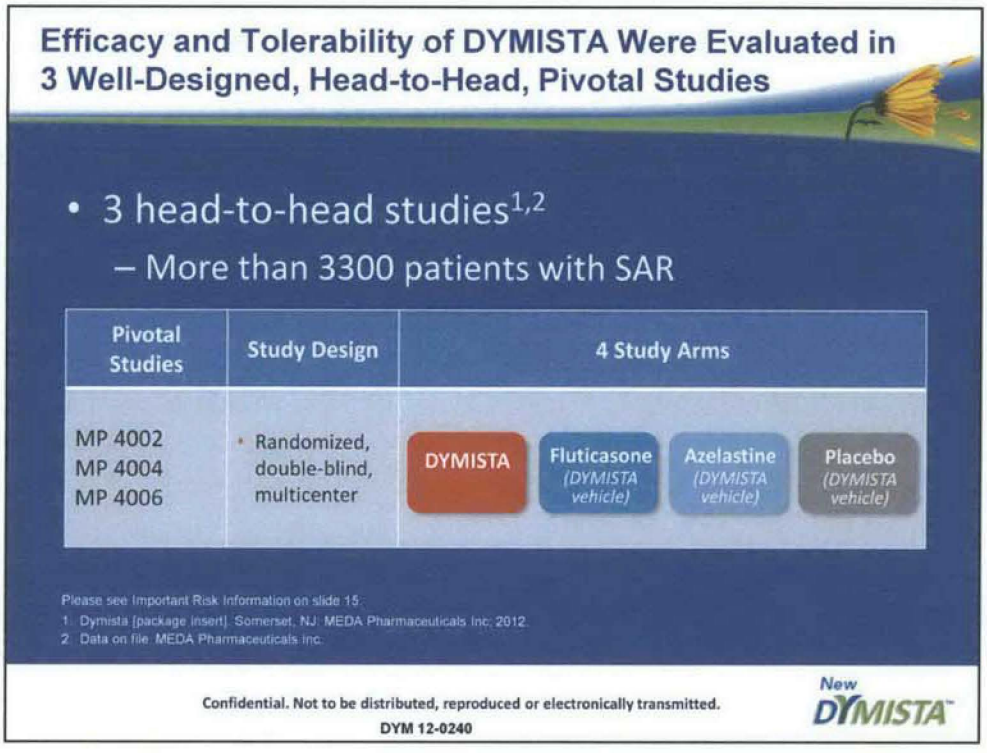
Study population: patients aged ≥12 years with symptomatic seasonal allergic rhinitis

All had positive skin-prick tests to relevant pollen

All patients had rTNSS scores of at least 8 out of 12 and a nasal congestion score of 2 out 3

At least one of the following: disruption of sleep, emotional distress, work and school interference

Speaker review rTNSS with the audience if needed



1. Dymista PI. Sect 14.1/p15/¶7-8 & p17/¶1 & table 2.

2. DOF. 4002 CSR, Synopsis. P 4./¶5 & 10; p5/¶1 & 4.

4004 CSR, Synopsis. P 4./¶7; p 5/¶3 & 6.

4004 CSR, Synopsis. P 4./¶6; p 5/¶2 & 5.

Efficacy and Tolerability of DYMISTA Were Evaluated in 3 Well-Designed, Head-to-Head, Pivotal Studies

1. Dymista PI. Sect 14.1/p15/¶7-8 & p17/¶1 & table 2.

Key Takeaway:

In a robust clinical development program, DYMISTA was evaluated in 3 head-to-head studies that enrolled more than 3300 patients with SAR[1,2]

Efficacy and tolerability of DYMISTA were compared with those of fluticasone, azelastine, and placebo (total of 4 study arms)

Additional Information:

Note that in these studies, fluticasone and azelastine were delivered using the same vehicle as DYMISTA

In all studies, DYMISTA, fluticasone, and azelastine were administered as 1 spray per nostril twice daily

The study population was 12 to 78 years of age

2. DOF. 4002 CSR, Synopsis. P 4./¶5 & 10; p5/¶1 & 4.

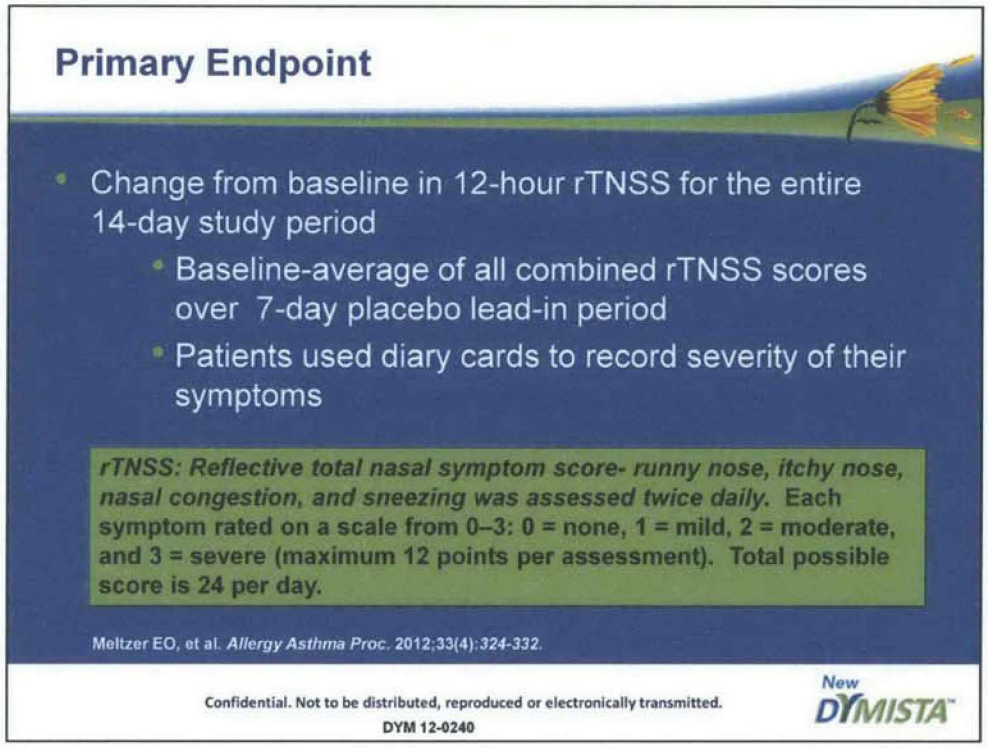
4004 CSR, Synopsis. P 4./¶7; p 5/¶3 & 6.

4004 CSR, Synopsis. P 4./¶6; p 5/¶2 & 5.

References:

1. Dymista [package insert]. Somerset, NJ: MEDA Pharmaceuticals Inc; 2012.

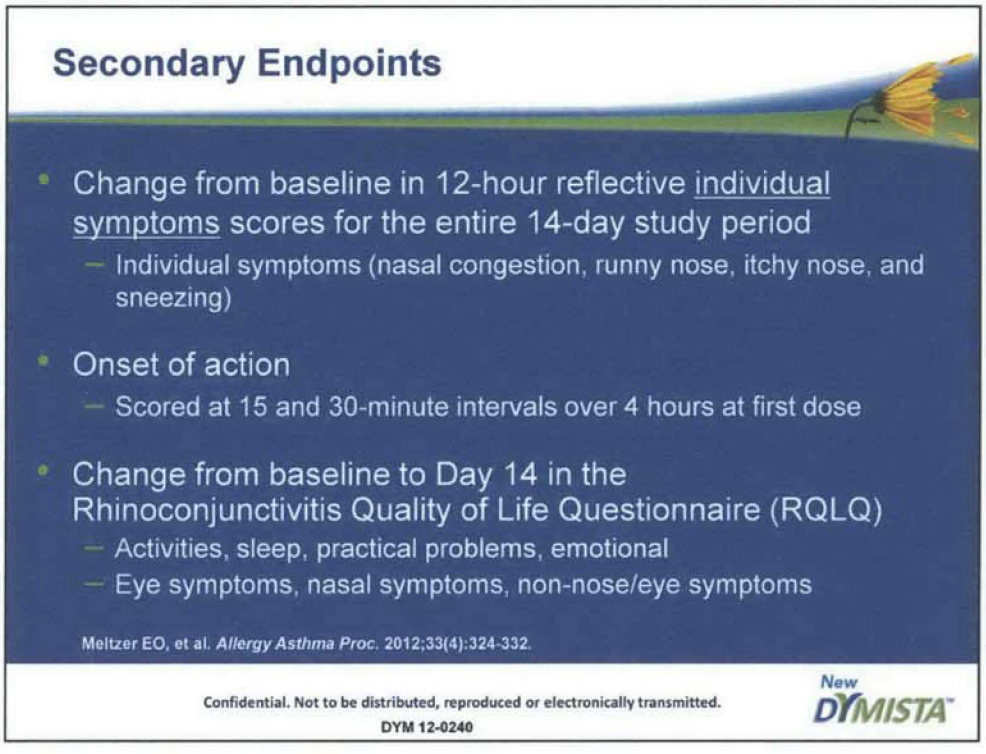
2. Data on file. MEDA Pharmaceuticals Inc.



Primary endpoint: change from baseline to Day 14 in combined 12-hour AM and PM rTNSS

Baseline-average of all combined rTNSS scores over 7-day placebo lead-in period, including the AM day 1 diary scores (predosing)

Patients used diary cards to record severity of their symptoms



Selected secondary endpoints:

Change from baseline to Day 14 in individual symptom scores

Onset of action

Change from baseline in the RQLQ (overall score and 7 individual domains) in subjects aged ≥18 years

Individual symptom scores—Recorded change from baseline for individual symptom (nasal congestion, runny nose, itchy nose, and sneezing)

Onset of action—Determined at the first office visit for each patient-nasal symptoms were scored at 15- to 30-minute intervals after the first dose of study medication during a 4-hour observation period.

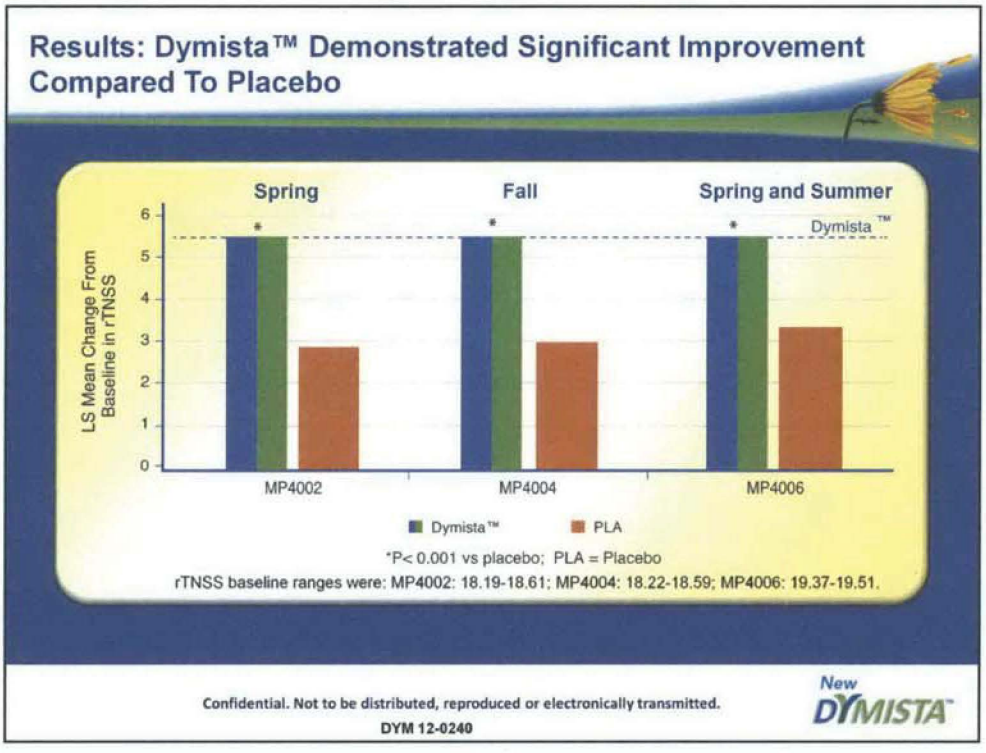
Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ)

28 items in 7 domains (activities, sleep, non-nose/eye symptoms, practical problems, nasal symptoms, eye symptoms, and emotional) evaluated on a 7-point scale where 0=no impairment and 6=maximum impairment.

Administered to patients aged ≥18 years.

An overall RQLQ score is calculated from the mean of all items in the instrument.

A change from baseline of at least 0.5 points is considered a clinically meaningful improvement.

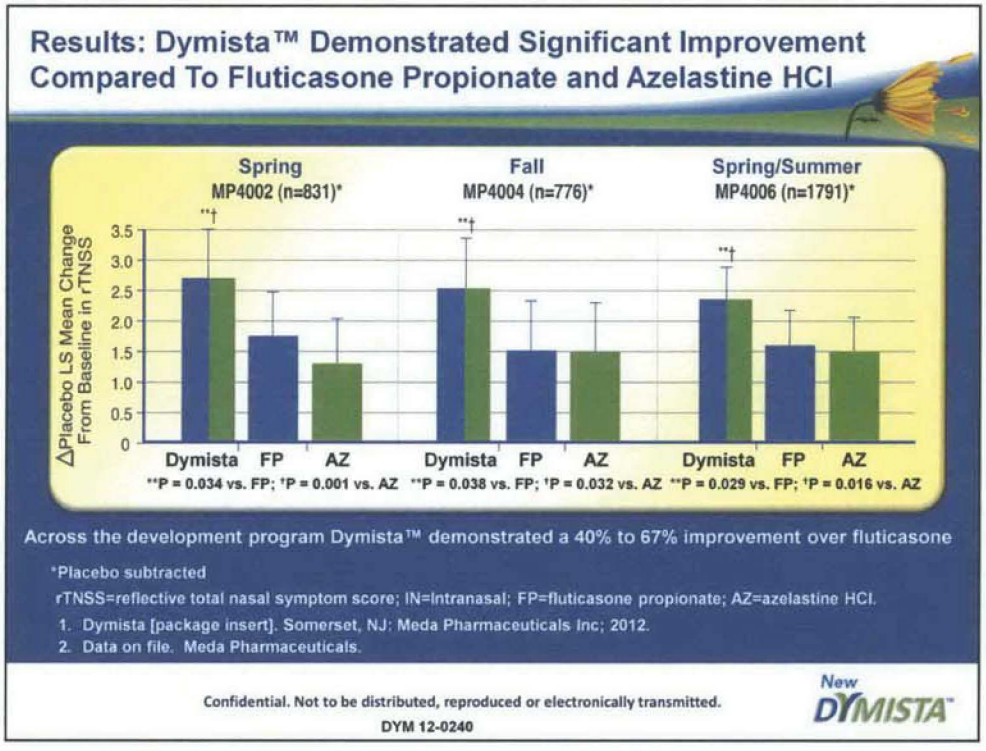


This graph represents the first part of the combination rule that Dymista™ was to be compared to placebo.

It also represents the typical study design of recently approved AR therapies.[1]

1. http://www.centerwatch.com/, Accessed 8.30.12

Dymista™ showed improvement in rTNSS regardless of the allergy season when compared to placebo.



This slide represents the findings of the 3 pivotal studies with respect to the primary endpoint rTNSS.

Across the 3 pivotal clinical trials, the improvement with Dymista™ ranged from 40% to 67% greater improvement relative to either comparator[1,2]

The azelastine HCl and fluticasone propionate comparators used the same device and vehicle as Dymista™ and are not commercially marketed[2]

Results shown are placebo subtracted

Speaker Note: You may initiate a discussion on the data seen in the slide above.

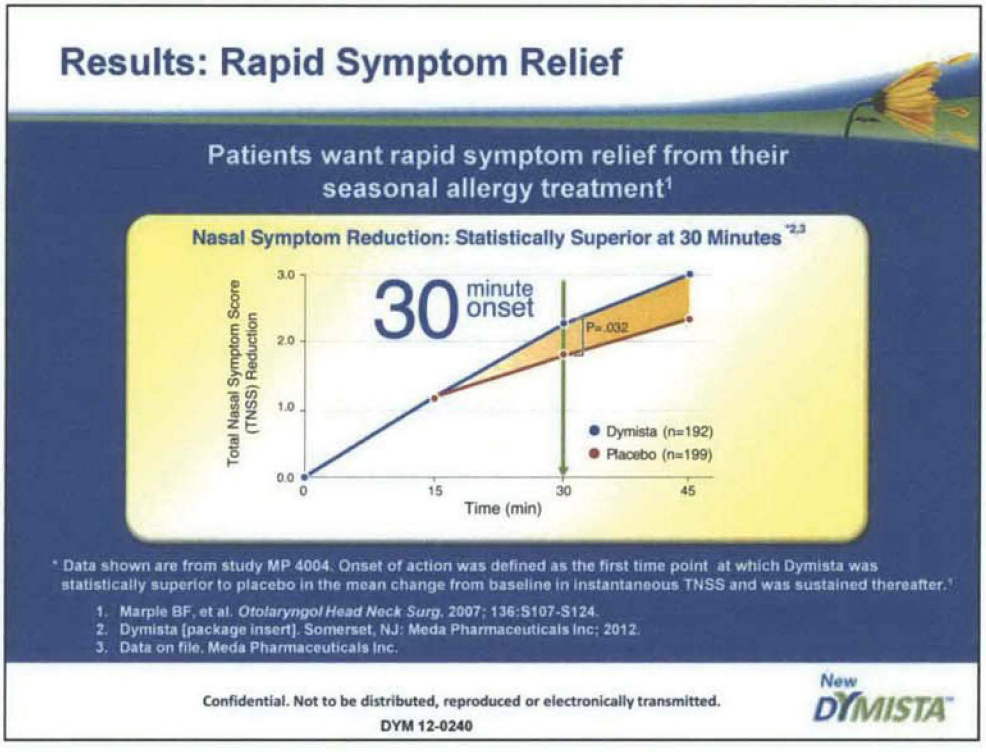
What are your thoughts regarding this data?

Are there patients under your care that may be candidates for Dymista™ now? Why?

What would Dymista™ be replacing? Why?

1. Dymista [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc; 2012.
2. Data on file. Meda Pharmaceuticals.

The FDA recognized that creating formulations of existing agents used together as a new single agent holds great promise for advancing patient care. Innovative drug, biological product, device combinations have the potential to make treatments safer, more effective, or more convenient or acceptable to patients.



Within 30 minutes of administration of Dymista™, patients began to experience significant relief of their nasal symptoms.

How important is rapid relief to your patients? What impact will this have on your practice/prescribing for SAR?

References

1. Marple BF, Fornadley JA, Patel AA, et al. Keys to successful management of patients with allergic rhinitis: focus on patient confidence, compliance, and satisfaction. *Otolaryngol Head Neck Surg.* 2007;136:S107-S124.

2. Dymista [package insert]. Somerset, NJ: Meda Pharmaceuticals Inc; 2012.

3. Data on file. Meda Pharmaceuticals Inc.

Are these typical quality of life issues that your AR patients present with? How do you address them currently?

This information is supportive of the more complete symptom relief seen with Dymista™.

In the 3 pivotal trials, Dymista™ demonstrated a statistically significant greater decrease from baseline in the overall RQLQ than placebo

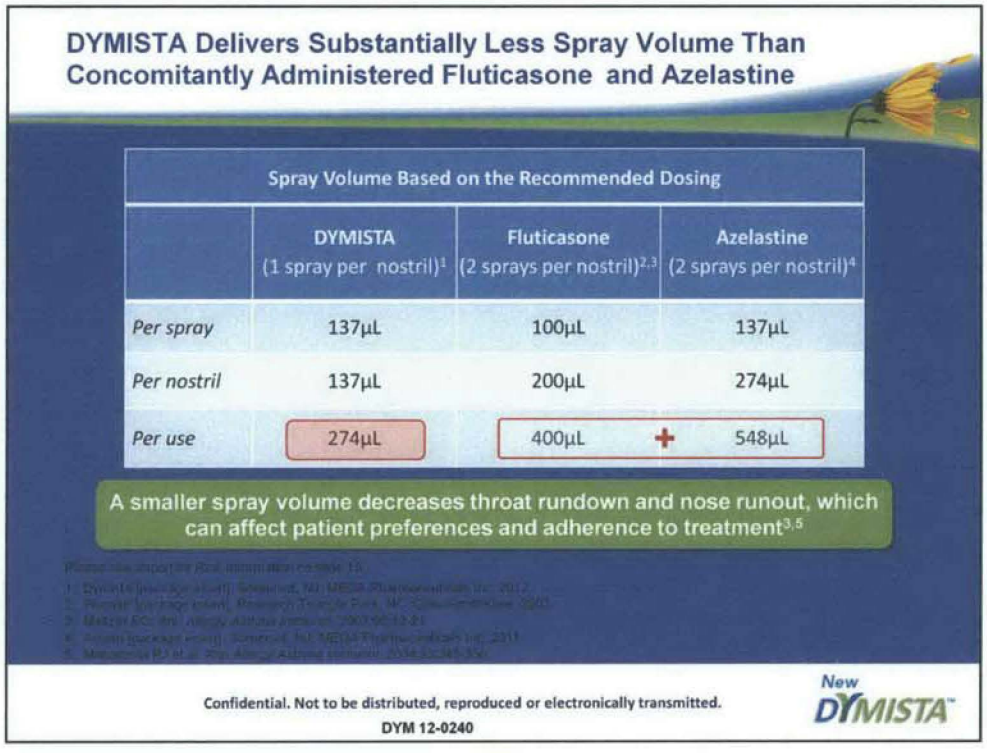
Ranged from -0.55 (95% CI: -0.72, -0.39) to -0.80 (95% CI: -1.05, -0.55)

The treatment differences between Dymista™ Nasal Spray and the monotherapies were less than the minimum important difference of 0.5 points.

1. Dymista PI. Sect 3/p2/¶6.

2. Flonase PI. 2004. p1/line 25; p11/lines 424-428.

4. Astelin PI. 2011. p1/¶3; p8/¶4.



3. Meltzer 2007. p 18/c2/¶4; p19/c1/¶1.

5. Mahadevia 2004. p 347/c1/¶3.

DYMISTA Delivers Substantially Less Spray Volume Than Concomitantly Administered Fluticasone and Azelastine

1. Dymista PI. Sect 3/p2/¶6.

Key Takeaway:

In comparison with the combination of fluticasone and azelastine—administered as 2 separate sprays— DYMISTA delivers substantially less volume in a single spray, which can minimize throat rundown and nose runout[1-4]

2. Flonase PI. 2004. p1/line 25; p11/lines 424-428.

4. Astelin PI. 2011. p1/¶3; p8/¶4.

Additional Information:

Patient surveys show that throat rundown and nose runout can affect patient preferences and adherence to treatment[4,5]

3. Meltzer 2007. p 18/c2/¶4; p19/c1/¶1.

It should be noted that practice guidelines state that there are inadequate data about the optimal interval between administration of an intranasal corticosteroid and an intranasal antihistamine, when administered as 2 separate sprays[6]

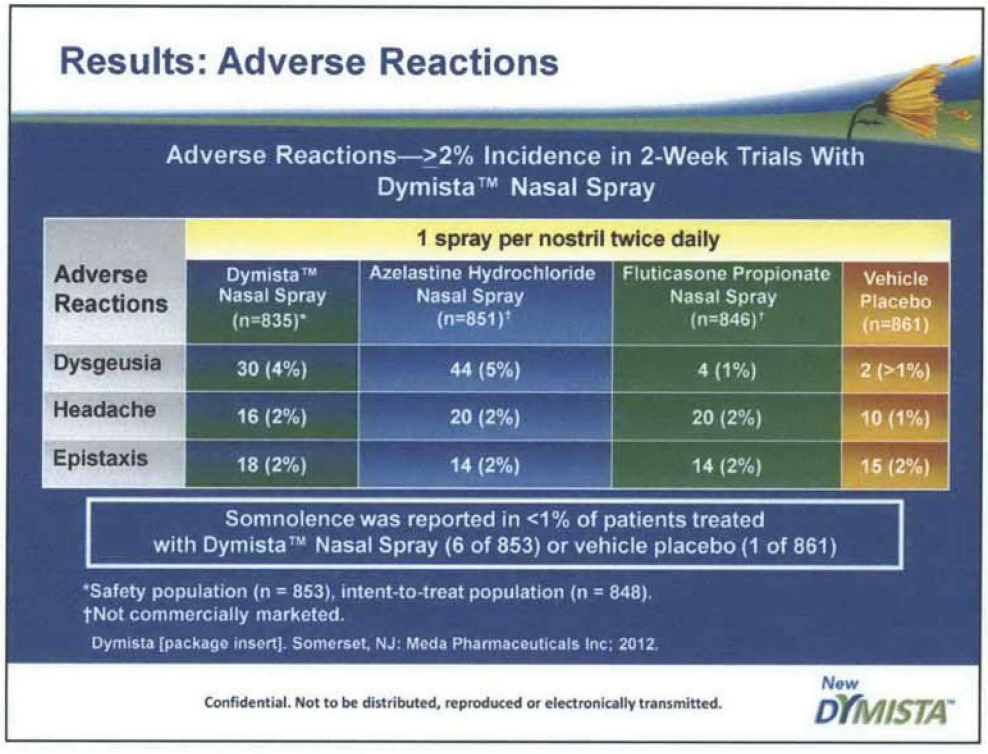
5. Mahadevia 2004. p 347/c1/¶3.

6. Wallace 2008. p S19/table VI.

References:

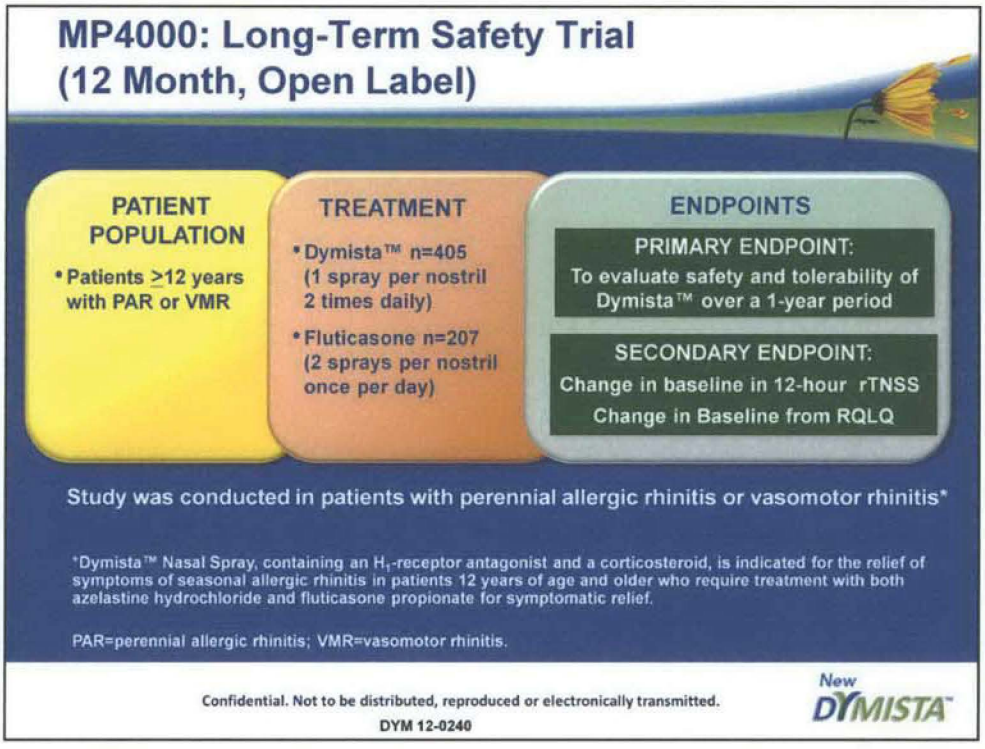
1. Dymista [package insert]. Somerset, NJ: MEDA Pharmaceuticals Inc; 2012.

2. Flonase [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2003.
3. Meltzer EO. Formulation considerations of intranasal corticosteroids for the treatment of allergic rhinitis. *Ann Allergy Asthma Immunol.* 2007;96:12-21.
4. Astelin [package insert]. Somerset, NJ: MEDA Pharmaceuticals Inc; 2011.
5. Mahadevia PJ, Shah S, Leibman C, Kleinman L, O'Dowd L. Patient preferences for sensory attributes of intranasal corticosteroids and willingness to adhere to prescribed therapy for allergic rhinitis: a conjoint analysis. *Ann Allergy Asthma Immunol.* 2004;93:345-350.
6. Wallace DV, Dykewicz MS, Bernstein DI, et al. The diagnosis and management of rhinitis: an updated practice parameter. *J Allergy Clin Immunol.* 2008;122(2):S1-S84.



This table contains adverse reactions reported with frequencies greater than or equal to 2% and more frequently than placebo in patients treated with Dymista™ Nasal Spray in the seasonal allergic rhinitis controlled clinical trials.

In these trials, somnolence was reported in <1% of patients treated with Dymista™ Nasal Spray (6 of 853) or vehicle placebo (1 of 861).



- Study Design—randomized, 12-month, open-label, active-controlled, parallel-group study in subjects with perennial allergic rhinitis or vasomotor rhinitis

  1-week screening period preceded the 12-month treatment period

  Qualified subjects were randomized in a 2:1 ratio to treatment with:

  Dymista™ (1 spray per nostril twice daily= total daily dose 548 mcg AZE; 200 mcg FP)

  Fluticasone (2 sprays per nostril once daily=total daily dose 200 mcg)

- Clinic visits at months 1, 3, 6, 9, and 12
- Phone contact at months 2, 4, 5, 7, 8, 10, and 11
- Frequency of subject-reported adverse events

  Monthly contact to review diary cards
- Focused nasal examinations

  Baseline, months 1, 3, 6, 9, and 12
- Slit-lamp examination by an ophthalmologist

  Baseline, months 6 and 12
- Laboratory assessments

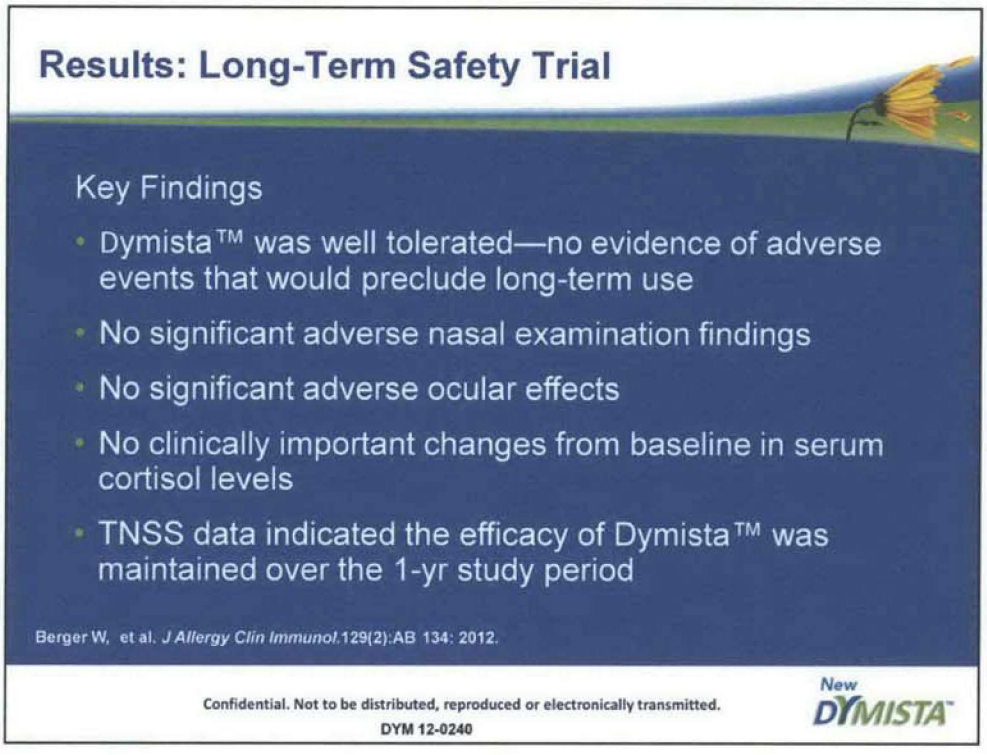
  Hematology, chemistry, urinalysis

  Fasting AM serum cortisol levels at selected sites

  Baseline, months 6 and 12

- Efficacy assessment

  PM rTNSS baseline, daily over entire study period



- The overall incidence of adverse reactions was 47% in the Dymista™ Nasal Spray treatment group and 44% in the fluticasone propionate nasal spray group.
- The most frequently reported adverse reactions (≥ 2%) with Dymista™ Nasal Spray were headache, pyrexia, cough, nasal congestion, rhinitis, dysgeusia (2.5%), viral infection, upper respiratory tract infection, pharyngitis, pain, diarrhea, and epistaxis.
- In the Dymista™ Nasal Spray treatment group, 7 patients (2%) had mild epistaxis and 1 patient (<1%) had moderate epistaxis. In the fluticasone propionate nasal spray treatment group, 1 patient (<1%) had mild epistaxis. No patients had reports of severe epistaxis.

- Somnolence was reported in <1% of patients treated with Dymista™ Nasal Spray

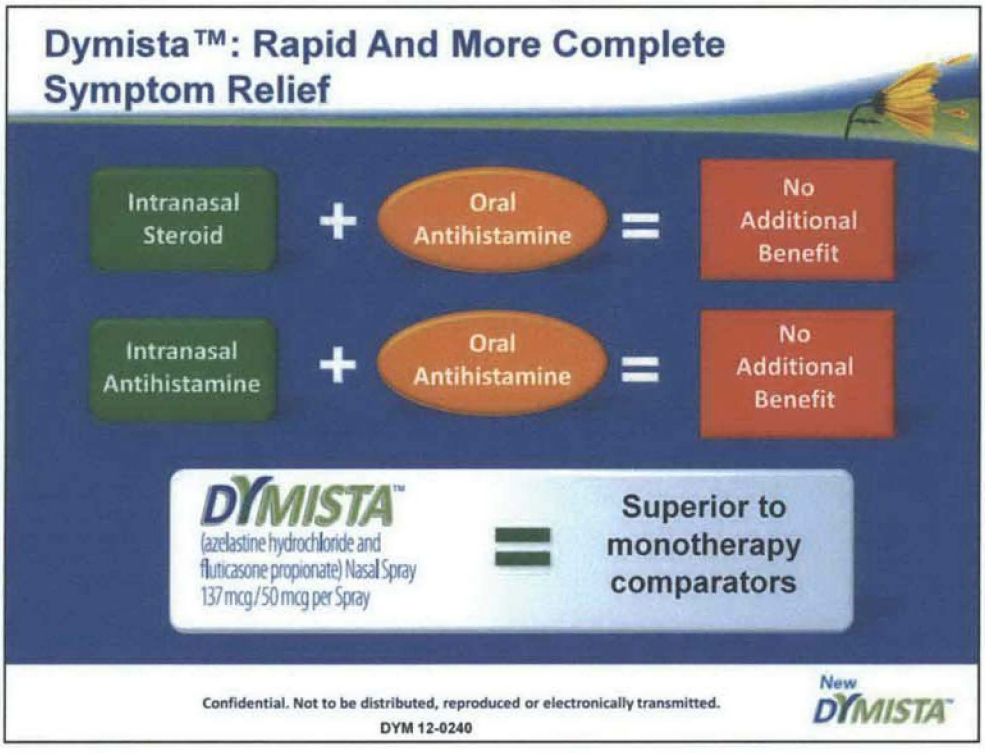
- Less then 1% of treatment groups had adverse ocular effects

  In the Dymista™ treatment group, 1 patient had increased intraocular pressure at Month 6. In addition, 3 patients had evidence of posterior subcapsular cataract at Month 6 and 1 at Month 12 (end of treatment).

  In the fluticasone propionate treatment group, 3 patients had evidence of posterior subcapsular cataract at Month 12 (end of treatment).

- Effects of Dymista™ on the HPA axis were evaluated in a subset of patients

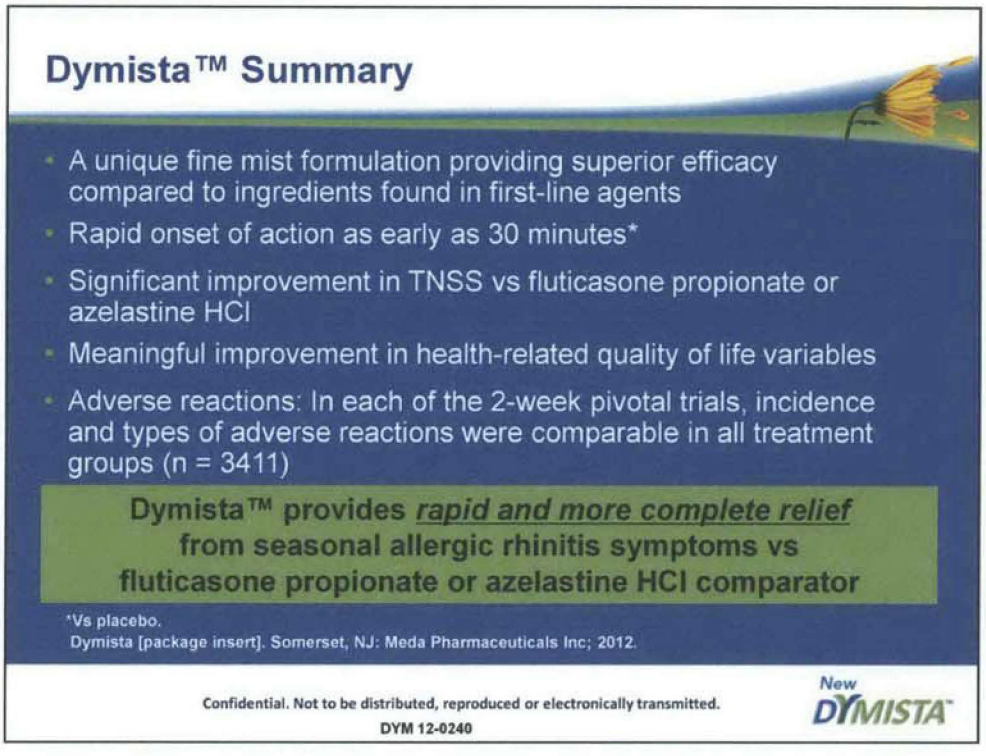
  Mean fasting serum cortisol levels were similar between patients treated with Dymista™ and patients treated with fluticasone at baseline, Month 6, and Month 12



- Previous clinical studies have shown that there is not an additional benefit in using an:
  - Intranasal steroid with an oral antihistamine
  - Intranasal antihistamine with an oral antihistamine

- Market research has shown that patients want:
  - Rapid (under 30 minute) relief from their symptoms of SAR
  - Are willing to use multiple therapies to seek a more complete relief from the symptoms of SAR
  - Are dissatisfied with their current therapies, especially during severe episodes

- Dymista™ has demonstrated in clinical trials:
  - Rapid onset of relief within 30 minutes compared to placebo
  - Across the 3 pivotal clinical trials, Dymista has shown more complete relief vs. active comparators
  - Treatment with Dymista also resulted in significant improvement in health-related quality of life (QoL) variables vs placebo



Dymista™ is a unique fine mist formulation that contains both the antihistaminic properties of azelastine HCl and anti-inflammatory properties of fluticasone propionate

Dymista™ demonstrated significant improvement in:

TNSS vs monotherapy comparators*

RQLQ vs placebo

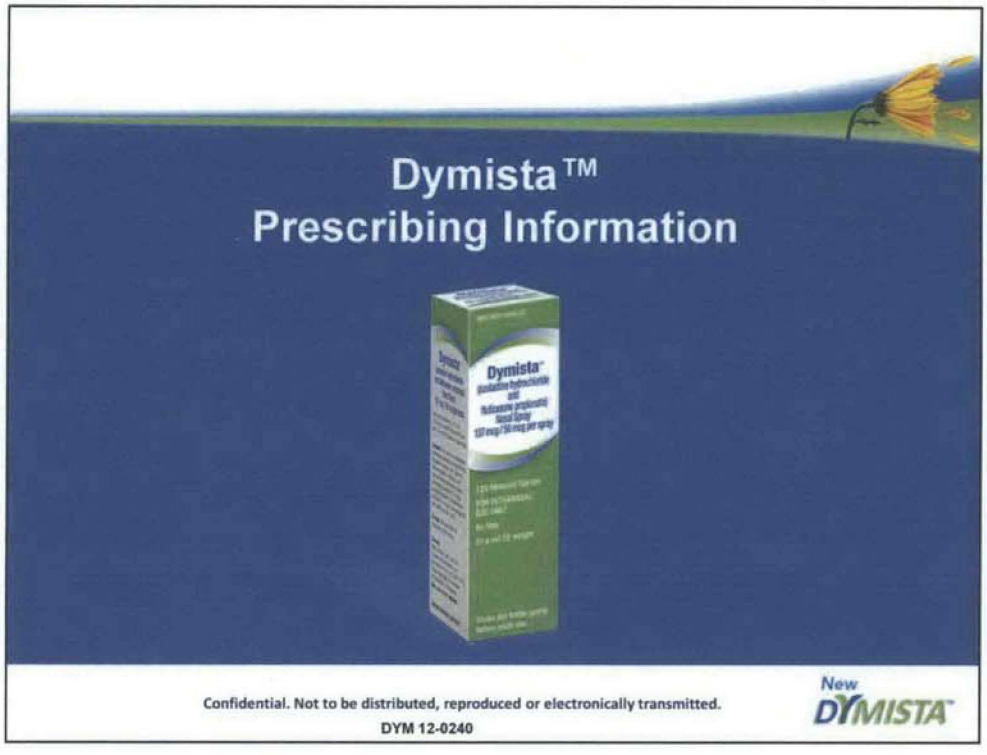
Onset of action vs placebo

Adverse reactions: In each of the 2-week pivotal trials, incidence and types of adverse reactions were comparable in all treatment groups (N=3411)

Conclusion:

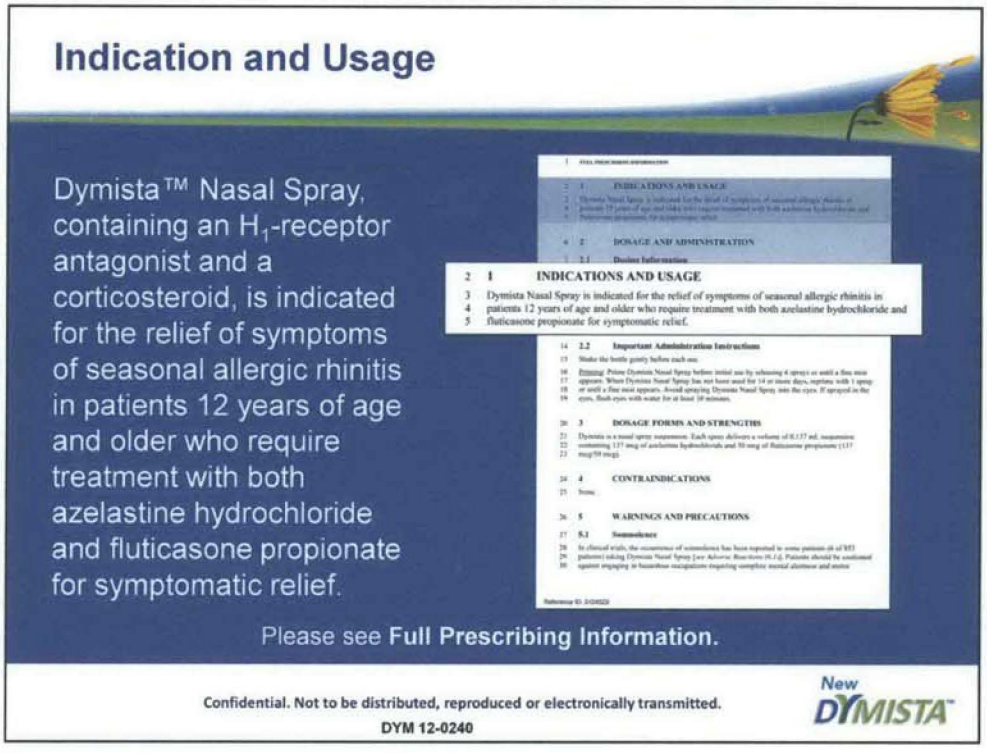
Dymista™ provides *rapid and more complete relief* from seasonal allergic rhinitis symptoms vs. fluticasone propionate or azelastine HCl

*The azelastine HCl and fluticasone propionate comparators used the same device and vehicle as Dymista and are not commercially marketed.

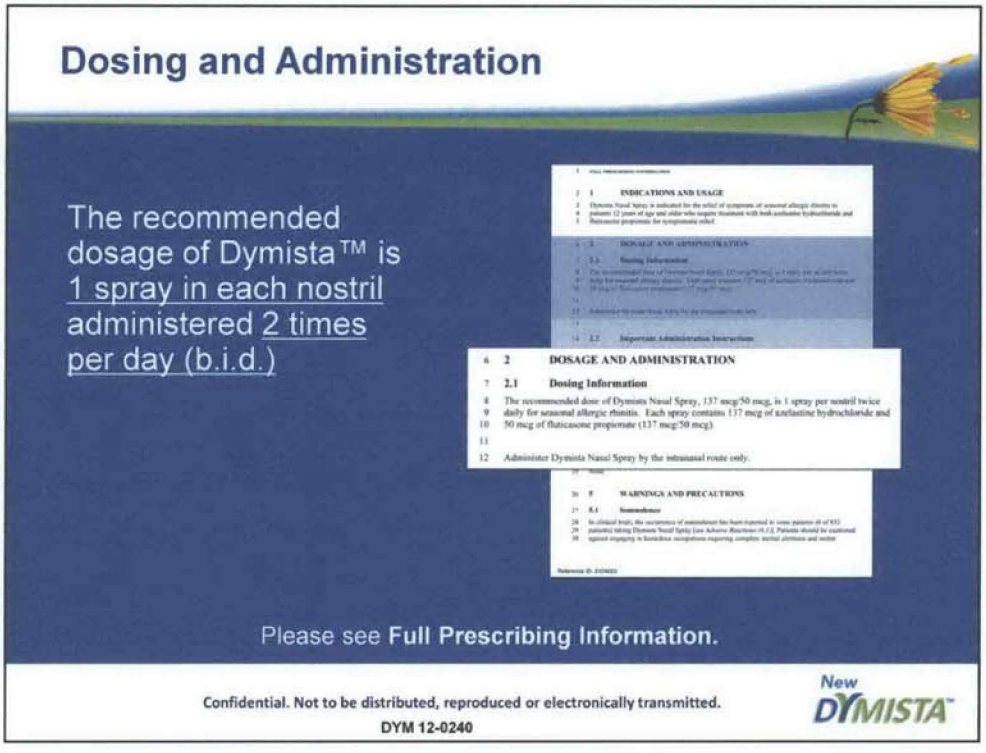


We will now review some highlights of the prescribing information (PI) for Dymista™.

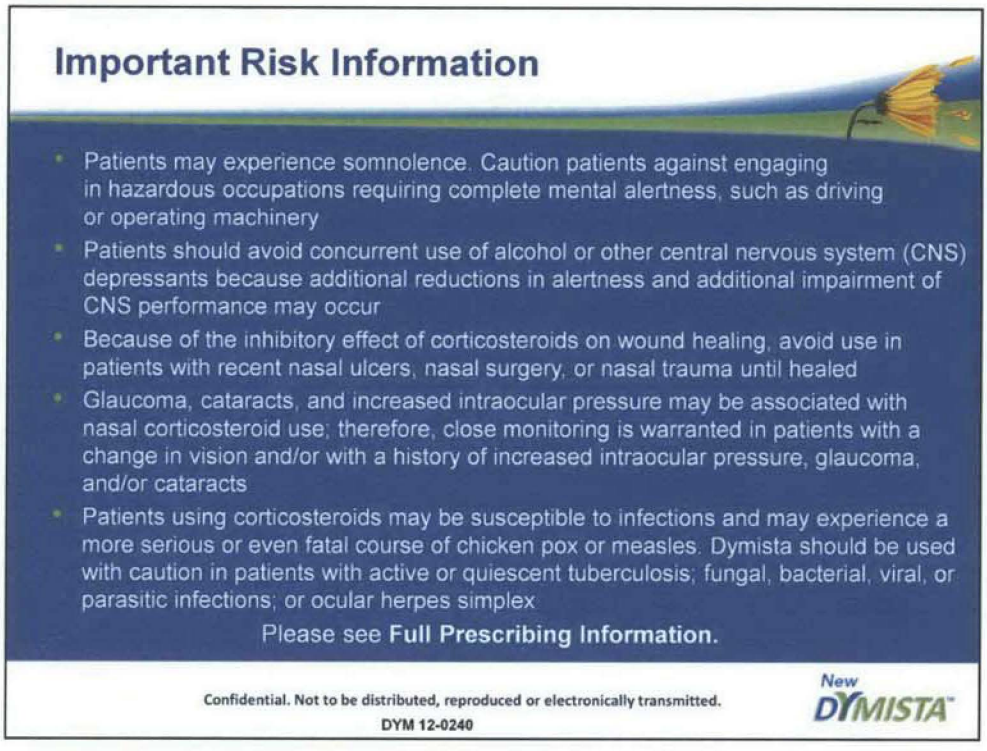
PIs to be distributed to the attendees.



Dymista™ Nasal Spray is indicated for the relief of the symptoms of seasonal allergic rhinitis (SAR) in patients 12 years of age and older who require treatment with both azelastine hydrochloride and fluticasone propionate for symptomatic relief.

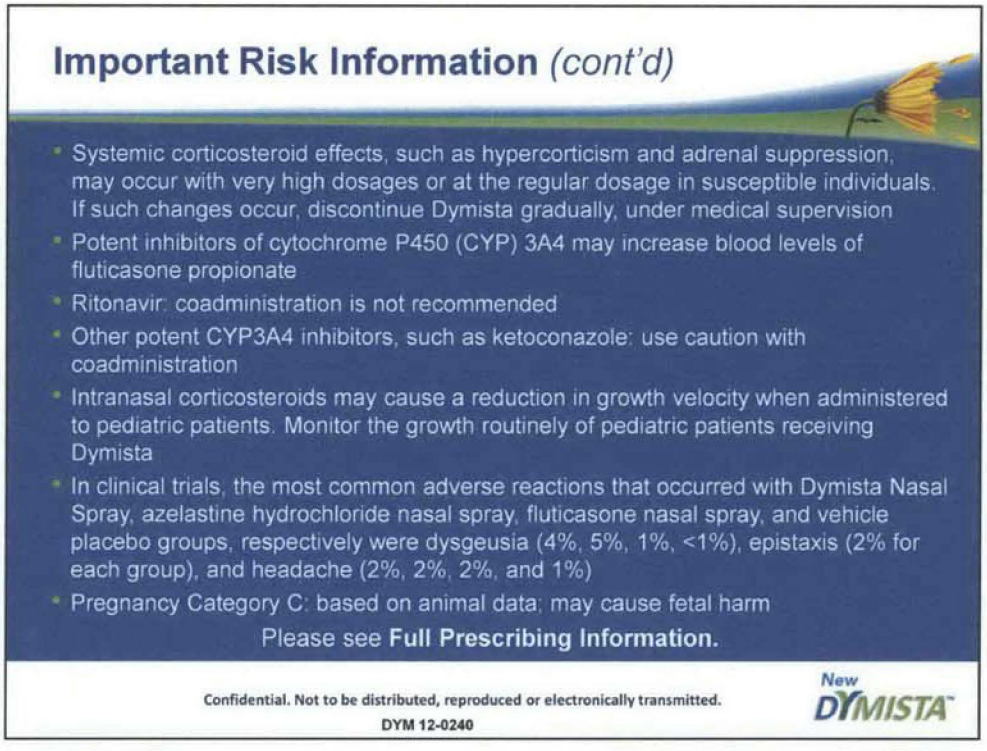


The recommended dosage is 1 spray in each nostril administered **2 times per day (b.i.d)**.



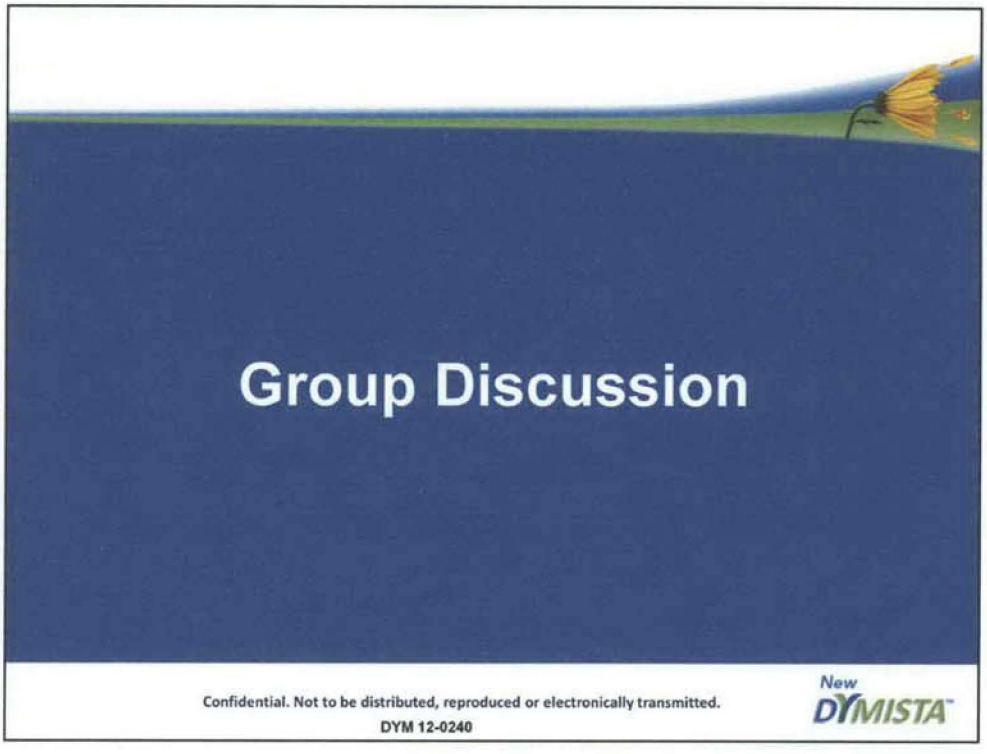
Important Risk Information

- Patients may experience somnolence. Caution patients against engaging in hazardous occupations requiring complete mental alertness, such as driving or operating machinery
- Patients should avoid concurrent use of alcohol or other central nervous system (CNS) depressants because additional reductions in alertness and additional impairment of CNS performance may occur
- Because of the inhibitory effect of corticosteroids on wound healing, avoid use in patients with recent nasal ulcers, nasal surgery, or nasal trauma until healed
- Glaucoma, cataracts, and increased intraocular pressure may be associated with nasal corticosteroid use; therefore, close monitoring is warranted in patients with a change in vision and/or with a history of increased intraocular pressure, glaucoma, and/or cataracts
- Patients using corticosteroids may be susceptible to infections and may experience a more serious or even fatal course of chicken pox or measles. Dymista should be used with caution in patients with active or quiescent tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex



Important Risk Information

- Systemic corticosteroid effects, such as hypercorticism and adrenal suppression, may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue Dymista gradually, under medical supervision
- Potent inhibitors of cytochrome P450 (CYP) 3A4 may increase blood levels of fluticasone propionate
- Ritonavir: coadministration is not recommended
- Other potent CYP3A4 inhibitors, such as ketoconazole: use caution with coadministration
- Intranasal corticosteroids may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth routinely of pediatric patients receiving Dymista
- In clinical trials, the most common adverse reactions that occurred with Dymista Nasal Spray, azelastine hydrochloride nasal spray, fluticasone nasal spray, and vehicle placebo groups, respectively were dysgeusia (4%, 5%, 1%, <1%), epistaxis (2% for each group), and headache (2%, 2%, 2%, and 1%)
- Pregnancy Category C: based on animal data; may cause fetal harm



Speaker opens up to the audience a discussion on the information just presented.