

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration					
TRANSMITTAL OF ADVERTISEMENTS AND PROMOTIONAL LABELING FOR DRUGS AND BIOLOGICS FOR HUMAN USE					
1. Date Submitted 06/17/2015			3. NDA/ANDA/AADA or BLA/PMA Type: NDA Number: 202236 <input checked="" type="checkbox"/> Single product <input type="checkbox"/> Multiple products		
2. Label Review Number (Biologics)			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 FDA 2253 is required by law. Reports are required for approved NDAs and ANDAs (21 CFR 314.81).					
4. Proprietary Name DYMISTA			5. Established Name azelastine hydrochloride and fluticasone propionate Product Code No.:		
6. Package Insert Date and ID Number (Latest final printed labeling) IN-023A6-05 02/2015			7. Manufacturer Name MEDA Pharmaceuticals Inc. License No. (Biologics):		
8. Advertisement / Promotional Labeling Materials					
a. Please check only one: <input type="checkbox"/> Professional <input checked="" type="checkbox"/> Consumer					
Material Type (use FDA codes) b.		Dissemination/ Publication Date c.		Material ID Code d.	
				Material Description e.	
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f. Comments					
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9. Applicant's (or Agent's) Return Address					
Address 1 (Street address, P.O. box, company name c/o) Meda Pharmaceuticals Inc.					
Address 2 (Apartment, suite, unit, building, floor, etc.) 265 Davidson Avenue					
City Somerset		State/Province/Region New Jersey			
Country USA		ZIP or Postal Code 08873-4120			
10. Responsible Official's (or Agent's)					
a. Telephone Number (Include area code) 732-564-2284					
b. FAX Number (Include area code) 732-564-2377					
c. Email Address lorna-jane.bremer@meda.us					
11. Typed Name and Title of Responsible Official or Agent Lorna-Jane Bremer, Senior Director Regulatory Affairs		12. Signature of Responsible Official or Agent 		13. Date 06/17/2015	
14. For CBER Products Only (Check one)					
<input type="checkbox"/> Draft <input type="checkbox"/> Final					

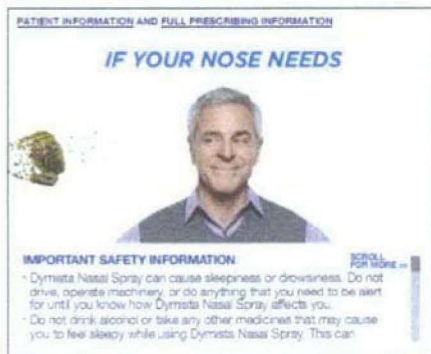
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PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

For seasonal nasal allergy sufferers 6 and older

ASK YOUR DOCTOR FOR



IMPORTANT SAFETY INFORMATION


- Dymista Nasal Spray can cause sleepiness or drowsiness. Do not drive, operate machinery, or do anything that you need to be alert for until you know how Dymista Nasal Spray affects you.
- Do not drink alcohol or take any other medicines that may cause you to feel sleepy while using Dymista Nasal Spray. This can

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PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

For seasonal nasal allergy sufferers 6 and older

DYMISTA
ciclesonide hydrochloride nasal spray
11 mcg/0.05 mL (0.22 mg/0.5 mL)
0.05% (w/v) ciclesonide




IMPORTANT SAFETY INFORMATION

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PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

DYMISTA HAS
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THE SAME ACTIVE INGREDIENT



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PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

**AS FLONASE®
(FLUTICASONE PROPIONATE)**



IMPORTANT SAFETY INFORMATION

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PLUS AN ANTIHISTAMINE




IMPORTANT SAFETY INFORMATION

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FOR RELIEF AS FAST AS




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PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

30 MINUTES FOR MOST PEOPLE*



IMPORTANT SAFETY INFORMATION

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- Do not drink alcohol or take any other medicines that may cause you to feel sleepy while using Dymista Nasal Spray. This can

PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

AND PAY LESS AT THE STORE.




IMPORTANT SAFETY INFORMATION [SCROLL FOR MORE >>](#)

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AS LITTLE AS \$14!*



*In addition to the copay benefit, a cash discount is available for those without insurance or Dymista coverage. Not available for any prescriptions covered by Medicaid, Medicare, Medicare Part D, or any other government insurance program. Additional restrictions apply.

IMPORTANT SAFETY INFORMATION [SCROLL FOR MORE >>](#)

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WHY WAIT?



IMPORTANT SAFETY INFORMATION [SCROLL FOR MORE >>](#)

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PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

ASK YOUR DOCTOR ABOUT



DYMISTA®
(azelastine hydrochloride and
fluticasone propionate) Nasal Spray
1.37 mcg/50 mcg per spray


IMPORTANT SAFETY INFORMATION

- Dymista Nasal Spray can cause sleepiness or drowsiness. Do not drive, operate machinery, or do anything that you need to be alert for until you know how Dymista Nasal Spray affects you.
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PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION

AND GET MORE.




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1.37 mcg/50 mcg per spray

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All trademarks are the property of their respective owners.

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PF-001 11/13/13 (Rev. 11/13/13) (DYM) (MKT) (11/13/13)

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(azelastine hydrochloride and
fluticasone propionate) Nasal Spray
1.37 mcg/50 mcg per spray

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Increase your chances of having serious side effects.
Dymista Nasal Spray may cause serious side effects including:

- Sleepiness or drowsiness
- Nasal Problems. Symptoms of nasal problems may include crusting in the nose, nosebleeds, runny nose, hole in the cartilage between your nose (nasal septal perforation). A whistling sound

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fluticasone propionate) Nasal Spray
1.17 mg/50 mcg per spray

BY PRESCRIPTION ONLY


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when you breathe may be a symptom of nasal septal perforation.

- **Slow wound healing.** You should not use Dymista Nasal Spray until your nose has healed if you have a sore in your nose, if you have had surgery on your nose, or if your nose has been injured.
- **Thrush (Candida), a fungal infection in your nose and throat.** Tell your doctor if you have any redness or white colored patches.

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fluticasone propionate) Nasal Spray
1.17 mg/50 mcg per spray

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Tell your doctor if you have any redness or white colored patches in your nose or mouth.

- **Eye problems, such as glaucoma or cataracts.** Some people may have eye problems, including glaucoma and cataracts. You should have regular eye exams when using Dymista Nasal Spray.

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1.17 mg/50 mcg per spray

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Immune system problems that may increase your risk of infections. Dymista Nasal Spray may cause problems with the way your immune system protects your body against infection and increase your risk of infection. Avoid contact with people who have contagious diseases such as chickenpox or measles while you use Dymista Nasal Spray. Symptoms of infection may include: fever, aches or pains, chills, feeling tired.

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- **Adrenal Insufficiency.** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal insufficiency may include: tiredness, weakness, nausea, vomiting, low blood pressure.
- **Slowed or delayed growth in children.** A child's growth should be checked regularly while using Dymista Nasal Spray.

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DYMISTA®
Lazareline hydrochloride and
Fluticasone propionate Nasal Spray
1.27 mg/50 mcg per Spray

BY PRESCRIPTION ONLY

All trademarks are the property of their respective owners.

Call your healthcare provider or get medical help right away if you have symptoms of any of the serious side effects listed above.

- The most common side effects with Dymista are changes in taste, nosebleeds, and headache.
- Tell your doctor if you have any side effect that bothers you or that does not go away.

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Call your healthcare provider or get medical help right away if you have symptoms of any of the serious side effects listed above.

- Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of Dymista Nasal Spray. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines.

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- ketoconazole, fluconazole, or itraconazole (for fungal infections)

Tell your doctor if you are pregnant or plan to become pregnant; it is not known if Dymista Nasal Spray will harm your unborn baby.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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DYMISTA®
 (azelastine hydrochloride and
 fluticasone propionate) Nasal Spray
 1.27 mcg/50 mcg per Spray


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All trademarks are the property of their respective owners.
 1-800-FDA-1088

APPROVED USES
 Dymista Nasal Spray is a prescription medicine used to treat symptoms of seasonal allergic rhinitis in people 6 years of age and older, who need treatment with both azelastine hydrochloride and fluticasone propionate. It helps reduce the symptoms of seasonal allergic rhinitis (inflammation of the lining of the nose), such as runny nose, stuffy nose, itching, and sneezing.

INDICATIONS AND USAGE
 Dymista Nasal Spray is indicated for the treatment of seasonal allergic rhinitis in people 6 years of age and older, who need treatment with both azelastine hydrochloride and fluticasone propionate.

PATIENT INFORMATION AND FULL PRESCRIBING INFORMATION



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