

## DYMISTA® (azelastine hydrochloride and fluticasone propionate) approved in children 6 to 11 years of age with seasonal allergic rhinitis

Meda announces the FDA approval of Dymista, a single formulation azelastine hydrochloride and fluticasone propionate nasal spray for the relief of symptoms of seasonal allergic rhinitis in patients 6 -11 years of age who require treatment with both components. Dymista was previously indicated only for adults and children 12 and older. The approved dosing for Dymista in children 6 to 11 is 1 spray/nostril BID (same as the dosing for adolescents and adults with SAR).

The efficacy and safety of Dymista was demonstrated in 2 pediatric trials where children 6 to 11 were treated with Dymista (1 spray per nostril twice daily). One of these trials was a 2-week trial comparing efficacy of Dymista and placebo in 304 children 6 to 11 years of age with SAR. The other trial was a 12-week open-label trial comparing the safety of Dymista and fluticasone nasal spray in 353 children 6 to 11 years of age with allergic rhinitis.

According to William Berger, MD, practicing allergist, Allergy and Asthma Associates of Southern California and Medical Director at Southern California Research Center, Mission Viejo, California, "The approval of Dymista for pediatric patients 6 to 11 years provides for a new, effective and safe treatment option for those suffering from Seasonal Allergic Rhinitis. Patients with SAR struggle to bring their symptoms under control; Dymista offers rapid onset of symptom improvement within 30 minutes of administration and allows for nasal symptom relief patients are seeking, all with a single nasal spray."

The efficacy and safety of Dymista has been documented in several studies involving over 4,000 patients, including long-term safety studies with more than 600 patients 12 years and older and in more than 350 patients aged 6 to 11 years.

## **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 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 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 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.
- 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.
- 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.

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• Slowed or delayed growth in children. A child's growth should be checked regularly while

using Dymista Nasal Spray.

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. 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, vitamins, and herbal supplements. Dymista Nasal Spray may affect

the way other medicines work, and other medicines may affect how Dymista Nasal Spray works.

Especially tell your healthcare provider if you take:

ritonavir (Norvir) or medicines that contain ritonavir (commonly used to treat HIV

infection or AIDS)

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

**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.

Please <u>click here</u> for Dymista Prescribing Information.

For further inquiries, please contact:

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