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US FDA approves over-the-counter, non-CFC-based Primatene® Mist; Patient advocacy groups object

The United States Food and Drug Administration (FDA) has approved Amphastar Pharmaceuticals' over-the-counter (OTC) Primatene® Mist (epinephrine inhalation aerosol bronchodilator suspension), which is delivered by a metered dose inhaler using a non-chlorofluorocarbon (non-CFC) propellant, for the temporary relief of mild symptoms of intermittent asthma in people ages 12 and older. The approval makes Primatene Mist the only asthma inhaler available without a prescription in the US. However, a variety groups that support patients with asthma have serious concerns about the approval.

A statement from the FDA

In support of its approval, the FDA issued a statement from FDA Commissioner Scott Gottlieb, MD, and Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research (CDER).

Past views on Primatene Mist

The statement explained that, "When Primatene Mist came off the market, many people objected to the removal of the product. Among those were patients with mild asthma who had been using the product successfully. There was also concern for underserved populations who had no other access to asthma treatment. At the same time, [the FDA] also heard from practitioners concerned with the product remaining on the market. They believed asthma patients could be harmed by self-medicating with an OTC product and that appropriate asthma care included regular care and supervised care by a health care provider, including the use of inhaled corticosteroids or other controller medications to reduce inflammation and the incidence of exacerbations."

Supporting their decision

The FDA statement noted those viewpoints were considered during the approval process. In addition, their statement said, "The scientific information we reviewed to approve the new version of OTC Primatene Mist shows there is a narrow population of those diagnosed with asthma that may benefit from having access to this type of OTC asthma inhaler. For the right patient, our analysis of the data, including new information that was developed since this product was previously on the market, shows that there are no serious safety concerns when Primatene Mist is used as directed."

A variety of cautions

The FDA statement also provided a variety of cautions including, "Asthma is a serious health condition that requires careful assessment and ongoing follow-up with a health care professional. [Primatene Mist] is approved only for those who have been diagnosed with asthma by a health care provider. [It] is not a replacement for prescription asthma treatments." The statement indicated the following text is included in the patient instructions. "Patients with more severe asthma should not rely on it. Instead, they should be working with their health care provider to ensure an appropriate treatment plan for their condition," along with a warning to seek medical care if the patient is using it regularly, as overuse of the product is a risk. Further, the statement said, "Even patients with mild asthma can have severe exacerbations so it's still important to consult a health care provider about appropriate care and have their condition reassessed. All patients who experience severe exacerbations should go to the emergency room right away. Asthma symptoms and recommended treatment regimens can vary from person to person. In addition, symptoms can change over time, requiring changes in treatment. It's important that consumers discuss asthma diagnoses and treatments with their health care providers before using any new asthma product, including an OTC product and they should not stop the treatment currently being used with-

out talking to them first. This is especially important because some prescription asthma medications are used to control the inflammation that causes asthma symptoms to develop and these medications must be used on a regular basis to be effective." The statement closed saying, "… we cannot stress enough the importance of seeing a health care provider for any chronic condition to receive a proper diagnosis and be put on a treatment plan that works for each individual patient."

Serious concerns from patient advocacy groups

However, a joint statement against the approval was issued by multiple asthma patient advocacy groups and community stakeholders. The group includes the Allergy & Asthma Network, American Association for Respiratory Care, American College of Allergy, Asthma & Immunology (ACAAI), American College of Chest Physicians (CHEST), American Lung Association, American Thoracic Society and Association of Asthma Educators.

Their statement, posted on the Allergy & Asthma Network's website, says the groups "believe the FDA's decision endangers people with asthma by suggesting asthma is a 'do-it-yourself' disease treatable with OTC medications."

The group statement also says that, "Primatene Mist does not treat asthma—instead it masks the symptoms that come from asthma. Furthermore, Primatene Mist's active ingredient is racemic epinephrine, which is not a recommended asthma treatment under the National Institutes of Health's 'Guidelines for the Diagnosis and Management of Asthma.'"

Putting patients at risk

The statement further says that, "Anyone with asthma should not consider Primatene Mist as a replacement for prescription asthma medications, including quick-relief albuterol inhalers and daily inhaled corticosteroids that prevent symptoms. If you have asthma and forgo or delay taking your prescribed asthma medication to use Primatene Mist, you are putting yourself at risk for a more serious flare and potentially causing long-term lung damage or even death." The statement adds, "Whether symptoms are mild, moderate or severe, people with asthma are encouraged to see their primary care doctor or a board-certified allergist or pulmonologist who can properly diagnose the disease and work with a healthcare team to outline an Asthma Action Plan that spells out how to treat asthma daily and what to do when symptoms worsen."

Eroding patient/clinician relationships

Representatives from several groups were quoted in the statement, including American Lung Association National President and CEO, Harold P. Wimmer, who identified an additional medical risk with the use of Primatene Mist saying, "The right asthma management plan can allow for a full and active life, and it requires strong communication between the patient and treating healthcare provider. The availability of and the reliance on over-the-counter medication like Primatene Mist in lieu of effective prescribed asthma medications erodes that communication and relationship, and it may also put patients at risk for excessive cardiac stimulation."

Available in early 2019

In a news release, Amphastar Pharmaceuticals explained that the patented formulation of Primatene Mist is made with the same active ingredient, epinephrine, which was used in the original Primatene Mist before it was removed from the market in 2011 to meet requirements of the Montreal Protocol. The product has other new features, including a built-in spray indicator and a metal canister that replaces the glass container used in the original Primatene Mist product. Amphastar expects Primatene Mist to be available in major drug stores across the US in early 2019.

References

Content for this article was based on and excerpted from:

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