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[Home](#) > FDA approves new version of Primatene Mist for mild asthma

Generic Name:

Epinephrine inhalation aerosol bronchodilator suspension

Trade Name:

Primatene Mist

Company:

Amphastar Pharmaceuticals

Notes:

On November 8, [FDA approved](#) a new version of epinephrine inhalation aerosol bronchodilator suspension known as Primatene Mist. The OTC metered-dose inhaler was reapproved to provide temporary relief for symptoms of mild, intermittent asthma in those who have been diagnosed with asthma by a health care provider.

The former OTC Primatene Mist was taken off the market in 2011 because it contained chlorofluorocarbon (CFC) propellants, which are known to deplete the ozone layer. This new version contains hydrofluoroalkane (HFAs) propellants, which are permitted under current international and U.S. law. Prescription-only inhalers that use different medications, such as albuterol and levalbuterol, also use HFAs as propellants.

In an FDA news release discussing concerns about the reapproval, FDA Commissioner Scott Gottlieb, MD, and Janet Woodcock, MD, director of the Center for Drug Evaluation and Research, stated that as the [OTC product is being reintroduced](#), the agency has taken steps to make sure consumers understand how to safely and effectively use the new product.

"Health professionals can ensure that patients understand and correctly apply the instructions for use. ... 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," they said. "You'll see that this risk is addressed in the instructions on how to use the product safely and a warning to seek medical care if the patient is using it regularly as overuse of the product is a risk."

They also noted that "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." But they pointed out that severe exacerbations can still occur even in individuals with mild asthma and that "any patient who experiences severe exacerbations should go to the emergency department right away."

It's also important to note that the new product looks different from the old version, with updated instructions for use that patients need to follow for the inhaler to work properly, they added.

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