

FDA approves return of popular Primatene Mist asthma inhaler

November 8 2018, by Linda A. Johnson



This undated product image provided by Amphastar shows Primatene Mist. A new version of the once-popular asthma inhaler Primatene Mist will soon return to U.S. stores. The Food and Drug Administration on Wednesday, Nov. 7, 2018, approved its over-the-counter aerosol inhaler for ages 12 and up. (Amphastar via AP)

A new version of the once-popular asthma inhaler Primatene Mist will soon return to U.S. stores.

The Food and Drug Administration approved the over-the-counter aerosol inhaler late Wednesday. It's for temporary relief of mild, intermittent asthma symptoms in people ages 12 and up.

The original Primatene Mist was discontinued seven years ago because the inhaler's ozone-depleting propellant had been banned. That version had been marketed for half a century, including in memorable TV ads.

The new product developed by Amphastar Pharmaceuticals uses a safer propellant. The inhaler will cost about \$25 and contain 160 doses. It should be available by the end of the year.

"Rescue inhalers" are meant to quickly relieve asthma symptoms such as wheezing, coughing, shortness of breath and chest tightness, which can be triggered by pollen, mold, dust mites, pet dander, stress or exercising in the cold.

Primatene Mist's active ingredient, the hormone epinephrine, relaxes muscles in the lungs to increase airflow. The product is the only FDA-approved over-the-counter inhaler. Numerous prescription rescue inhalers, containing the medicine albuterol or levalbuterol, are available.

In a statement Thursday, FDA officials noted concerns that some people may inappropriately use or overuse the new inhaler. The agency said it should not be substituted for prescription treatments or used by people with severe asthma.

Primatene Mist was pulled from stores in 2011, but it still has many fans, including tens of thousands who have liked Facebook pages advocating its return. TV ads for the old version touted its speedy relief with endorsements from athletes such as Bob Gibson and Jackie Joyner-Kersey, or by showing a gasping person getting relief as a stopwatch ticked off 15 seconds.

An Amphastar subsidiary bought rights to the product's name and spent several years improving it.

The new version contains less alcohol and epinephrine, which can increase heart rate, especially if the inhaler is used too much. Side effects include tremors and dizziness.

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