

Primatene[®] Mist (epinephrine) – New over-the-counter drug (OTC) approval

- On November 8, 2018, the [FDA announced the approval](#) of [Amphastar Pharmaceuticals' Primatene Mist \(epinephrine\)](#), for the temporary relief of mild symptoms of intermittent asthma (ie, wheezing, tightness of chest, and shortness of breath) in adults and children 12 years of age and older.
 - Primatene Mist is not a replacement for prescription asthma treatments.
 - Patients with asthma should be under the care of a health care professional.
- A previous version of OTC Primatene Mist was taken off the market in 2011 because it contained chlorofluorocarbon propellants. This new version of OTC Primatene Mist contains hydrofluoroalkane propellants, which are permitted under current U.S. law.
- Warnings of Primatene Mist include for oral inhalation only; and an asthma alert: because asthma may be life threatening, patients should see a doctor if they are not getting better in 20 minutes, get worse, need more than 8 inhalations in 24 hours, and/or have more than 2 asthma attacks in a week. These may be signs that a patient's asthma is getting worse.
- Primatene Mist should not be used unless a doctor has diagnosed a patient with asthma; or if the patient is taking a prescription monoamine oxidase inhibitor (MAOI), or for 2 weeks after stopping the MAOI drug.
- Patients should stop use and ask a doctor if: their asthma is getting worse; they have difficulty sleeping; they have a rapid heartbeat; or they have tremors, nervousness, or seizure.
- The recommended dose of Primatene Mist for adults and children \geq 12 years of age is 1 – 2 inhalations for each dose.
 - Patients should start with one inhalation and wait at least 1 minute. If not relieved, a second inhalation can be administered.
 - Patients should wait at least 4 hours between doses and should not exceed 8 inhalations in 24 hours.
- Amphastar Pharmaceuticals plans to launch Primatene Mist in early 2019. Primatene Mist will be available as a 0.125 mg epinephrine per spray inhalation aerosol that contains 160 sprays.