Generic Name:
Epinephrine
Trade Name:
Primatene Mist
Company:
Armstrong Pharmaceuticals
Notes:

As reported earlier this year in Pharmacy Today, Primatene Mist, the only FDA-approved OTC inhaler for temporary relief of occasional symptoms of mild asthma on the U.S. market, is being withdrawn after December 31 of this year.

FDA is concerned that current users of the product may be self-treating their conditions. Since all other currently available products for asthma require a prescription, Primatene Mist users need to act now to see a prescriber and obtain the medications they need. In addition, the agency is concerned that many of these patients are likely uninsured and may have financial difficulties in seeing a prescriber and paying for prescription products.

Primatene Mist uses chlorofluorocarbon (CFC) as its propellant, and the U.S. is phasing out CFC use because of obligations made under the Montreal Protocol on Substances that Deplete the Ozone Layer. The phaseout of CFC-containing inhalers was announced by FDA in 2008, and many manufacturers of prescription inhalers have already converted their propellants to environmentally friendly hydrofluoroalkane (HFA).

FDA said during a September 22 news conference that two prescription inhalers will be withdrawn from the market on December 31, 2013, if they are not reformulated with HFA or another acceptable propellant. They are Combivent Inhalation Aerosol (albuterol/ipratropium?Boehringer Ingelheim) and Maxair Autohaler (pirbuterol?Graceway Pharmaceuticals).

Pharmacists should advise patients currently using OTC inhalers to contact their health provider to have symptoms evaluated and obtain prescription asthma medications if needed. FDA has provided several helpful counseling tips for patients currently using OTC epinephrine inhalers. These include telling patients to ask a family member, friend, or co-worker about a doctor they use and would recommend, helping patients with payment options and company assistance plans, and educating patients on use of their new prescription inhalers once they are transitioned to these products. The last point is especially important, an FDA official said, as the replacement products may taste and feel different.

Medication Monitor Categories:
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