Cipla Issues Voluntary Nationwide Recall of 6 Batches of Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation) Due to Container Defect

Date: 07/07/2023

At Magellan Rx Management, we want to help you receive the best possible care. Visit our drug recall site for details: https://www1.magellanrx.com/drug-recalls/

About this recall:
Cipla Limited announced that its wholly-owned subsidiary, Cipla US, is voluntarily recalling 6 batches of Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation) manufactured in November 2021 to the consumer level. The company is initiating a recall in the US due to a market complaint for 1 single inhaler (Batch Number - IB20056), where leakage was observed through the inhaler valve. Out of an abundance of precaution, the above mentioned 6 batches manufactured using the same lot of valves are being recalled. The product is packaged in 17ml plain aluminum aerosol canisters integrated with a dose counter, coupled with a plastic actuator and dust cap. Each pack claims 200 metered inhalations. Associated codes are NDC-69097-142-60. These six batches were distributed Nationwide to wholesalers and retailers.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found below.

The product is used for the treatment and prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise induced bronchospasm.

What this means to you:
There is a reasonable probability that failure to deliver the recommended dose to treat the respiratory symptoms of an acute asthma exacerbation such as wheezing, coughing, shortness of breath, and bronchospasms, due to device defect, may be life-threatening. There were no adverse events reported for Albuterol Sulfate Inhalation Aerosol 90 mcg related to this recall.

Consumers with questions adverse reactions or quality problems regarding these six batches can contact Cipla Customer Service at 844- CIPLAUS (844-247-5287) M-F 8:30-5:00 EST, or email cipla.cs@cipla.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being conducted with the knowledge of the United States (US) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cipla-issues-voluntary-nationwide-recall-six-batches-albuterol-sulfate-inhalation-aerosol-90-mcg-200

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.