DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

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

7/06/2023

Mumbai, India July 6, 2023/ New Jersey, USA July 6, 2023 – Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla"), today announced that its wholly-owned subsidiary Cipla US is voluntarily recalling six batches of Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation) manufactured in November 2021 to the consumer level.

Product Name	Batch No.	Expiry Date
Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20045	Nov.2023
Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20055	Nov.2023
Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20056	Nov.2023
Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20057	Nov.2023
Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20059	Nov.2023
Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20072	Nov.2023

Risk Statement: There is a reasonable probability that failure to deliver the recommended dose to treat the respiratory symptoms of an acute asthma exacerbations 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.

The company is initiating a recall in the US due to a market complaint for one 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 used for the treatment and prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise induced bronchospasm. The product is packaged in 17ml plain

aluminium aerosol canister integrated with dose counter coupled with plastic actuator and dust cap, each pack claims 200 metered inhalations and associated codes NDC-69097-142-60. These 6 batches were distributed Nationwide to wholesalers and retailers.

Cipla is notifying its distributors and customers by letter and is arranging for return and replacement of all recalled products. **Consumers/distributors/retailers** that have **product** from these 6 batches which are being recalled should **stop using/return to place of purchase/discard.**

Consumers with questions adverse reactions or quality problems regarding these 6 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:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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 U.S. Food and Drug Administration.

Cipla maintains stringent quality processes to assess quality defects and safety issues. Cipla conducts regular investigation and assessment by committees consisting of subject-matter experts, quality management, and medical safety experts.

For queries, please contact:

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Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cipla-issues-voluntary-nationwide-recall-six-batches-albuterol-sulfate-inhalation-aerosol-90-mcg-200?utm_medium=email&utm_source=govdelivery