Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-038-CG
July 7, 2023

FDA announced that, **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.

RECOMMENDATIONS

1. **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**.

2. 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**.

3. 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.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

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

Summary:

Company Announcement Date: July 06, 2023
FDA Publish Date: July 07, 2023
Product Type: Drugs
Reason for Announcement: Failure to deliver the recommended dose
Company Name: Cipla
Brand Name: Cipla
Product Description: Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation)

Company Announcement

FOR IMMEDIATE RELEASE - 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.

Sr. No.	Product Name	Batch No.	Expiry Date
1.	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20045	Nov.2023
2.	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20055	Nov.2023
3.	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20056	Nov.2023
4.	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20057	Nov.2023
5.	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20059	Nov.2023
6.	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 MI)	IB20072	Nov.2023

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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**

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