COMMUNICATION

COM-2023-039

11
JULY
2023

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

07.07.2023

Drug Information:

National Drug Code

69097-0142-060

Product Description

ALBUTEROL SULFATE INHALATION AERSOSOL, 90MCG (200 METERED INHALATION)

Batch Number

REFER TO TABLE INCLUDED IN THIS NOTIFICATION.

Expiration Date

NOVEMBER 2023

Company:

CIPLA LIMITED

QUESTIONS

Call CIPLA at 844.247.5287 Monday – Friday from 8:30 a.m. to 5:00 p.m. ET or email at cipla.cs@cipla.com

Albuterol Sulfate Inhalation Aerosol

It is for this reason that we are notifying you that on 07.07.2023 the US Food and Drug Administration published a drug recall for the following product(s): Albuterol sulfate inhalation aerosol, 90mcg (200 metered inhalation).

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Cipla Limited is voluntarily recalling six batches of albuterol inhalation aerosol, 90mcg (200 metered inhalation) manufactured in November 2021 to the consumer level.

The recall is being made because of damage to a single inhaler (IB20056), where leakage was observed through the inhaler valve. There is a possibility that failure to deliver the recommended dose for acute asthma exacerbations may be life-threatening due to device defect. The 6 batches that were manufactured using the same lot of valves are being recalled for precautionary purposes.

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 should stop using the product.

Recalled Products

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

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2023-039 July 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). Cipla Issues Voluntary Nationwide Recall of Six Batches of Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation) Due to Container Defect. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/cipla-issues-voluntary-nationwide-recall-six-batches-albuterol-sulfate-inhalation-aerosol-90-mcg-200
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program