

Contacts

Primary

Name Robert Kalis RPh
Address Publix Pharmacy
 5200 SW 34th St
 Gainesville, FL 32608
 US

Fax**Class** RPh**Type** HCP**Salutation** Mr.**Specialty****Gender** Male**Phone****Contact****Phone****Mobile** (352) 375-1496**Phone****E-Mail** None**Misc****Greeting****Degree** RPh**National
Identifier**Case
Information**Language** English**Department** Medical Information**Request Via** Unsolicited**Division** CIP-AE**Status** Completed**Case Type** AE PC**Case Product Code** Ipratropium Bromide and Albuterol Sulfate**Case Product
Trade Name** Ipratropium Bromide and Albuterol Sulfate Inhalation Solution**Case Product
Generic Desc** Ipratropium Bromide and Albuterol Sulfate**Priority** Medium**Source** Phone**Entry Period** Business Hours**Handling** Phone**Service Rep** MARY**Call Center** MICC**Referred To** MARY**Original Case Owner** MARY**Misc Data****Rep ID****Rep Name****Rep Type****Rep Phone****Rep Email****MSL ID****MSL Name****MSL Type****MSL Phone****MSL Email****Entered** 04/Apr/2023 6:16 PM**Received** 04/Apr/2023 12:00 AM**Completed** 09/Apr/2023 7:16 AM**1st Received** 04/Apr/2023 12:00 AM**1st Completed** 05/Apr/2023 9:41 PM**Local Date Received** 04/Apr/2023**Reference Case
Number** 2023US01989

| Client Data | Field | Text Information | Numeric | Date | Yes/No |
|----------------------|--|---|---|-------------|--------|
| | QCed by and Date Forwarded to Cipla | Rakshith D | | 05/Apr/2023 | Yes |
| | Urgent notification (Yes/No) | | | | No |
| | Prepaid mailer initiated/Date of prepaid mailer initiated | | | | No |
| | Pregnancy (Yes/No) | | | | No |
| | LOE (Yes/No) | | | | No |
| | Lot/Expiration | NP / NP | | | |
| | Case Status(Open/Closed) | Closed | | 07/Apr/2023 | |
| | Initial Case Validity (Yes/No)/Case became valid a | | | | Yes |
| | Medical device (Yes/No) | | | | No |
| | Medical device number | NA | | | |
| Product | Code | Trade Name | Generic Desc | Detail | Class |
| | Ipratropium Bromide and Albuterol Sulfate | Ipratropium Bromide and Albuterol Sulfate Inhalation Solution | Ipratropium Bromide and Albuterol Sulfate | | |
| Off Label? | No | | | | |
| Disease Area | | | | | |
| Therapeutic Area | | | | | |
| Category | Safety | | | | |
| Category Explanation | | | | | |
| Topic | Adverse Event | | | | |
| Topic Explanation | | | | | |
| Question | <p>Initial AE Received:</p> <p>Patient informed the pharmacist that she used some of the vials of Ipratropium bromide and Albuterol sulfate inhalant solution manufactured by Cipla which were foaming up a lot after nebulising them. He confirmed that she experienced this issue only in some vial and not in all the vials.</p> | | | | |
| Question Notes | | | | | |
| Abstract | No abstracts have been assigned to this case | | | | |
| Response | <p>Edited by MARY on Tue Apr 04 2023 16:47:05 GMT-0400 (Eastern Daylight Time)</p> <p>1. PATIENT INFORMATION:</p> <p>A. DOB/AGE: NP / NP</p> <p>B. HEIGHT (INCHES): NP</p> <p>C. WEIGHT (POUNDS): NP</p> <p>2. DATE SALES REPRESENTATIVE INFORMED:</p> <p>3. SUSPECT PRODUCT INFORMATION:</p> <p>A. INDICATION: NP</p> <p>B. PRODUCT START DATE: NP</p> <p>C. PRODUCT STOP DATE: Ongoing</p> <p>4. DEATH INFORMATION NA</p> <p>A. DATE OF DEATH (If died): NA</p> <p>B. AUTOPSY (YES/NO/UNKNOWN): NA</p> | | | | |

C. DATE OF AUTOPSY: NA

5. SERIOUSNESS CRITERIA (DEATH/LIFE-THREATENING/NEW OR PROLONGED HOSPITALIZATION/DISABILITY/CONGENITAL ANOMALY/IME):

6. EVENT INFORMATION:

A. EVENT TERM: Patient used some of the vials of Ipratropium bromide and Albuterol sulfate inhalant solution which were foaming up a lot after nebulising them.

B. START DATE OF EVENT: 2023

C. STOP DATE OF EVENT: NA

D. OUTCOME (NOT RECOVERED/UNKNOWN/RECOVERING/RECOVERED): NA

E. DE-CHALLENGE (POSITIVE/NEGATIVE/UNKNOWN/NOT-APPLICABLE): NA

F. RE-CHALLENGE (POSITIVE/NEGATIVE/UNKNOWN/NOT-APPLICABLE): NA

7. PAST MEDICAL HISTORY: NP

8. ALLERGIES: NP

9. CONCOMITANT MEDICATIONS: NP

A. CONCOMITANT NAME: NP

B. CONCOMITANT INDICATION: NP

C. CONCOMITANT DOSE/FREQUENCY: NP

D. CONCOMITANT START DATE: NP

E. CONCOMITANT STOP DATE: NP

10. PREGNANCY INFORMATION (YES or NO): NA

IF YES

A. GESTATION PERIOD: NA

B. PREGNANCY OUTCOME: NA

C. LAST MENSTRUAL PERIOD DATE: NA

D. EXPECTED DATE OF DELIVERY: NA

E. NUMBER OF CHILDREN (PRIOR TO PREGNANCY): NA

11. DESCRIPTION OF COURSE OF EVENTS:

Initial Report Date: 04-APR-2023

Information received from a pharmacist concerning a female patient who was using Ipratropium bromide and Albuterol sulfate inhalant solution manufactured by Cipla with NDC: 69097-840-64. He refused to provide the patient's age, ethnicity, height and weight.

He refused to provide the patient's medical history, concurrent conditions and concomitant medication details.

The patient commenced Ipratropium bromide and Albuterol sulfate inhalant solution at strength (0.5 mg / 3 mg per 3 ml). He did not have the lot number and expiry date and refused to provide the dose, frequency, route, start date and indication.

Patient informed the pharmacist that in 2023, she used some of the vials of Ipratropium bromide and Albuterol sulfate inhalant solution manufactured by Cipla which were foaming up a lot after nebulising them. He confirmed that she experienced this issue only in some vial and not in all the vials. He refused to provide any details regarding treatment taken, lab tests conducted and its results.

Action taken with the suspect product was ongoing.

He informed that the patient had purchased 3 boxes of 60 vials each on 28-FEB-2023. Informed him that ideally, the medication should not be foaming and to let the patient know, not to use the product which was foaming.

Although the caller initially provided the consent for call back, but later refused to provide any AE information. Also, he refused to provide the patient details and mentioned that he would instead ask the her to call Cipla.

Case reference number was shared as CIPPC23-0954 and call back number was provided as (866) 604-3268.

| | QC done by RAKSHITHD on Wed Apr 05 2023 21:39:50 GMT-0400 (Eastern Daylight Time) | | | | | | |
|---------------|---|--------------------|---------------------|------------|-----------------|---------------|---------------|
| Manufacturer | Cipla | Sub Classification | | | | | |
| Resolutions | <table><tr><th>Resolution</th><th>Resolution Type</th></tr><tr><td>AE Documented</td><td>Transfer</td></tr></table> | | | Resolution | Resolution Type | AE Documented | Transfer |
| Resolution | Resolution Type | | | | | | |
| AE Documented | Transfer | | | | | | |
| Documents | No documents have been attached to this case | | | | | | |
| Owner | MARY | | | | | | |
| QStatus | Completed | Completed On | 05/Apr/2023 9:40 PM | | | | |
| Crosslink | <table><tr><th>Case</th><th>Contact Name</th></tr><tr><td>CIPPC23-0954</td><td>Kalis, Robert</td></tr></table> | | | Case | Contact Name | CIPPC23-0954 | Kalis, Robert |
| Case | Contact Name | | | | | | |
| CIPPC23-0954 | Kalis, Robert | | | | | | |

****Note: All Long Dates are in LOCAL Time Zone.**