

<b>Contacts</b>	<b>Primary</b>	
	<b>Name</b> Charu Gupta <b>Address</b> House number 289, Arun Vihar Sector-28, Yamuna Enclave, Uttar Pradesh Noida 201303 IN  <b>Fax</b> <b>Class</b> CON <b>Type</b> Consumer <b>Salutation</b> Ms. <b>Specialty</b>	<b>Gender</b> Female <b>Phone</b> <b>Contact Phone</b> <b>Mobile Phone</b> 9810706989 <b>E-Mail</b> charu.gupta556@gmail.com <b>Misc</b> <b>Greeting</b> <b>Degree</b> <b>National Identifier</b>
<b>Case Information</b>	<b>Language</b> English <b>Department</b> Medical Information <b>Request Via</b> Unsolicited	
	<b>Division</b> CIP-AE <b>Status</b> Completed	
	<b>Case Type</b> AE PC <b>Case Product Trade Name</b> SEROFLO 250 DC <b>Priority</b> Medium <b>Entry Period</b> Business Hours	<b>Case Product Code</b> SEROFLO 250 DC <b>Case Product Generic Desc</b> SEROFLO 250 DC <b>Source</b> Phone <b>Handling</b> Phone
	<b>Service Rep</b> CHETHANA <b>Referred To</b> CHETHANA <b>Misc Data</b>	
	<b>Call Center</b> MICC <b>Original Case Owner</b> CHETHANA	
	<b>Rep ID</b> <b>Rep Type</b> <b>Rep Email</b>	<b>Rep Name</b> <b>Rep Phone</b>
	<b>MSL ID</b> <b>MSL Type</b> <b>MSL Email</b>	<b>MSL Name</b> <b>MSL Phone</b>
	<b>Entered</b> 12/Apr/2023 4:30 AM <b>Completed</b> 25/Apr/2023 6:12 AM <b>1st Completed</b> 13/Apr/2023 4:42 PM	
	<b>Received</b> 12/Apr/2023 4:30 AM <b>1st Received</b> 12/Apr/2023 4:30 AM <b>Local Date Received</b> 12/Apr/2023 <b>Reference Case Number</b> 2023IN02076	

Client Data	Field	Text Information	Numeric	Date	Yes/No
	QCed by and Date Forwarded to Cipla	Rakshith D		13/Apr/2023	Yes
	Urgent notification (Yes/ No)				No
	Prepaid mailer initiated/Date of prepaid mailer in				No
	Pregnancy (Yes/No)				No
	LOE (Yes/No)				Yes
	Lot/Expiration	Seroflo 250 Inhalers = Inhaler 1: SN1211 / SEP-2023; Inhaler 2: SN10876 / APR-2023; Seroflo 250 Synchrobreathe Inhaler = GB21287 / APR-2024			
	Case Status(Open/Closed)	Closed		15/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
	SEROFLO 250 DC	SEROFLO 250 DC	SEROFLO 250 DC		
Off Label?	No				
Disease Area					
Therapeutic Area					
Category	Safety				
Category Explanation					
Topic	Adverse Event				
Topic Explanation					
Question	<p>Initial AE Received:</p> <p>Patient noticed that Seroflo 250 DC Inhaler was not effective as it was not releasing the dose properly because of which she switched to Seroflo 250 Synchrobreathe Inhalers. However, even after switching the inhalers, she again noticed that Seroflo 250 Synchrobreathe inhaler was not releasing the dose properly and she did not feel that the medication was reaching her lungs. She confirmed that she did not experience anything unusual apart from this.</p>				
Question Notes					
Abstract	No abstracts have been assigned to this case				
Response	<p>Edited by CHETHANA on Wed Apr 12 2023 04:34:01 GMT-0400 (Eastern Daylight Time)</p> <p>1. PATIENT INFORMATION:</p> <p>A. DOB/AGE: Unk / Unk            B. HEIGHT (INCHES): Unk            C. WEIGHT (POUNDS): Unk</p> <p>2. DATE SALES REPRESENTATIVE INFORMED:</p> <p>3. SUSPECT PRODUCT INFORMATION:</p> <p>1. Seroflo 250 DC Inhaler            2. Seroflo 250 Synchrobreathe Inhaler</p> <p>A. INDICATION:</p> <p>1. Bronchitis            2. Bronchitis</p>				

## B. PRODUCT START DATE:

1. NP (She mentioned that she started using it long time ago, but did not provide a specific date)
2. NOV-2022

## C. PRODUCT STOP DATE:

1. NOV-2022
2. Ongoing

## 4. DEATH INFORMATION NA

A. DATE OF DEATH (If died): NA

B. AUTOPSY (YES/NO/UNKNOWN): NA

C. DATE OF AUTOPSY: NA

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

## 6. EVENT INFORMATION:

## A. EVENT TERM:

1. Seroflo 250 DC Inhaler was not effective / Patient did not feel that the medication from Seroflo 250 Synchrobreathe Inhaler was reaching her lungs
2. Patient used Seroflo 250 DC Inhaler and Seroflo 250 Synchrobreathe Inhaler which were not releasing the dose properly

## B. START DATE OF EVENT:

1. Unk
2. Unk

## C. STOP DATE OF EVENT:

1. NA
2. NA

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

1. NA
2. NA

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

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

## 7. PAST MEDICAL HISTORY: Unk

8. ALLERGIES: Allergic to pollution and dust

9. CONCOMITANT MEDICATIONS: Unk

A. CONCOMITANT NAME: Unk

B. CONCOMITANT INDICATION: Unk

C. CONCOMITANT DOSE/FREQUENCY: Unk

D. CONCOMITANT START DATE: UNK

E. CONCOMITANT STOP DATE: UNK

## 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: 12-APR-2023

Information received from a female patient who was using Seroflo 250 DC Inhaler and Seroflo 250 Symbreathe Inhaler manufactured by Cipla. Age, height and weight were unknown.

The medical history, concurrent conditions and concomitant medication details were unknown.

The patient informed that she started using Seroflo 250 DC Inhaler long time ago, but did not provide a specific date and started using Seroflo 250 Symbreathe Inhaler via inhalation route in NOV-2022 for bronchitis. Regarding the dose and frequency, she informed that she uses both the inhalers during her exercises and whenever required. She mentioned that she uses the inhalers approximately 15 days in a month and provided the following lot numbers and expiry dates:

Seroflo 250 DC Inhaler:

Inhaler 1: SN1211 / SEP-2023

Inhaler 2: SN10876 / APR-2023

Seroflo 250 Symbreathe Inhaler: GB21287 / APR-2024

On an unknown date, the patient noticed that Seroflo 250 DC Inhaler was not effective as it was not releasing the dose properly because of which she switched to Seroflo 250 Symbreathe Inhalers. However, even after switching the inhalers, she again noticed that Seroflo 250 Symbreathe inhaler was not releasing the dose properly and she did not feel that the medication was reaching her lungs. She confirmed that she did not experience anything unusual apart from this. Regarding treatments, she mentioned that she does yoga, breathing exercise and meditation so that she can manage even though the inhaler was not releasing the dose properly. Lab tests were unknown.

Action taken with Seroflo 250 DC Inhaler was stopped in NOV-2022 and action taken with Seroflo 250 Symbreathe Inhaler was ongoing.

She agreed to share photographs of complaint sample to [ciplaproductqueries@cipla.com](mailto:ciplaproductqueries@cipla.com) and [drugsafety@cipla.com](mailto:drugsafety@cipla.com).

She provided the consent for call back.

Shared case number CIPPC23-1021 for her reference.

Before any further information could be collected, she disconnected the call stating that she was getting a call from her office.

QC done by RAKSHITHD on Thu Apr 13 2023 16:39:23 GMT-0400 (Eastern Daylight Time)

Edited by MARYSURESH on Thu Apr 20 2023 09:20:36 GMT-0400 (Eastern Daylight Time)

Follow up was made on 20-APR-2023

First follow up call was made to collect below AE details:

1. Date of birth, age at onset of the events, weight, height of the patient?
2. Any other medical conditions of the patient?
3. Any lab details or investigations?
4. Use of any other medications by the patient? (if yes, then start date, stop date and indication)

However, call did not connect.

Edited by SMISHRA on Mon Apr 24 2023 04:48:53 GMT-0400 (Eastern Daylight Time)

Follow up was made on 24-APR-2023

Second follow up call was made to collect below AE details:

1. Date of birth, age at onset of the events, weight, height of the patient?

	2. Any other medical conditions of the patient? 3. Any lab details or investigations? 4. Use of any other medications by the patient? (if yes, then start date, stop date and indication) However, line was busy. Edited by SMISHRA on Tue Apr 25 2023 06:11:23 GMT-0400 (Eastern Daylight Time) Follow up was made on 25-APR-2023 Third follow up call was made to collect below AE details: 1. Date of birth, age at onset of the events, weight, height of the patient? 2. Any other medical conditions of the patient? 3. Any lab details or investigations? 4. Use of any other medications by the patient? (if yes, then start date, stop date and indication) However, line was busy.						
<b>Manufacturer</b>	Cipla	<b>Sub Classification</b>					
<b>Resolutions</b>	<table border="1"> <thead> <tr> <th>Resolution</th> <th>Resolution Type</th> </tr> </thead> <tbody> <tr> <td>AE Documented</td> <td>Transfer</td> </tr> </tbody> </table>			Resolution	Resolution Type	AE Documented	Transfer
Resolution	Resolution Type						
AE Documented	Transfer						
<b>Documents</b>	No documents have been attached to this case						
<b>Owner</b>	CHETHANA						
<b>QStatus</b>	Completed	<b>Completed On</b>	25/Apr/2023 6:12 AM				
<b>Crosslink</b>	<table border="1"> <thead> <tr> <th>Case</th> <th>Contact Name</th> </tr> </thead> <tbody> <tr> <td>CIPPC23-1021</td> <td>Gupta, Charu</td> </tr> </tbody> </table>			Case	Contact Name	CIPPC23-1021	Gupta, Charu
Case	Contact Name						
CIPPC23-1021	Gupta, Charu						

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