SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
UNKNOWN	UNITED STATES	06	MAY	2025	1 Days	Male	Unk	07	MAY	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant, IMPORTANT MEDICAL EVENT
CUROSURF OCCLUDED ET TUBE FOLLOWING DOSE ADMINISTRATION [Endotracheal intubation complication]
CUROSURF OCCLUDED ET TUBE FOLLOWING DOSE ADMINISTRATION [Product complaint]

Case Description: Case reference number 2025CHF03235 is a spontaneous case report sent by an other health professional via sales representative (hospital sales specialist) and received through US affiliate (local country

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☒ OTHER: IMPORTANT

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) CUROSURF (PORACTANT ALFA) Endotracheopulmonary instillation, suspension, 80 milligram per millilitre

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 8.8 milliliter	#1) Unknown

17. INDICATION(S) FOR USE
#1) RESPIRATORY DISTRESS (Respiratory distress)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 06-MAY-2025 12:10:00 / Unknown	#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates | Type of History / Notes | Description
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Chiesi Farmaceutici SpA
via Palermo, 26/A
Parma, 43122 ITALY

26. REMARKS
Medically Confirmed: Yes
World Wide #: US-CHIESI-2025CHF03235

24b. MFR CONTROL NO.
2025CHF03235

24c. DATE RECEIVED BY MANUFACTURER
07-MAY-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
15-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER

UNITED STATES

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

number: CHIEMC-10103) which refers to a male patient of aged 1 day.

Concomitant medications and past medical/drug history have not been provided.

On 06-May-2025 at 12:10, the patient was administered Curosurf [poractant alfa] (endotracheopulmonary instillation, suspension, 80 mg/ml) at 8.8 ml for respiratory distress.

It was reported that the first dose had been given with no issues. Subsequently, a second dose was administered. This second dose was given in two halves. During the administration of the last half of the second dose on 07-May-2025 at 09:50, an occlusion was noticed in the endotracheal (ET) tube. As a result of this occlusion, the patient was extubated. To resolve the issue, the patient was then re-intubated (endotracheal tube obstruction) (seriousness: IME (important medical event) and pharmaceutical product complaint.

The event of endotracheal tube obstruction was considered as serious as it was included in the EMA IME list.

On 07-May-2025 at 09:55, the patient recovered from the event of endotracheal tube obstruction.

At the time of this report, the patient was not recovered yet from the event of pharmaceutical product complaint.

The reporter considered the event of endotracheal tube obstruction certainly related and did not assess the causal relationship between the event of pharmaceutical product complaint and Curosurf.

Further information is expected.

Case comments:
This 1 day old male neonate experienced “Curosurf occluded ET tube following dose administration” (endotracheal tube obstruction) (pharmaceutical product complaint) during administration of Curosurf [poractant alfa] (endotracheopulmonary instillation, suspension, 80 mg/ml) at a dose of 8.8 ml for respiratory distress.
The event “Curosurf occluded ET tube following dose administration” was assessed as serious (seriousness criterion: important medical event).
The event of endotracheal tube obstruction was considered as serious as it is included in the EMA IME list.
The event “Curosurf occluded ET tube following dose administration” was considered as non-serious by convention.
The endotracheal tube obstruction is a listed adverse reaction for Curosurf according to the reference safety information.
The pharmaceutical product complaint was considered as unlisted by convention.
The adverse reaction of endotracheal tube obstruction is expected as per US Prescribing Information.
The pharmaceutical product complaint was considered as unexpected by convention.
The adverse reaction of endotracheal tube obstruction is expected as per Canadian Product Monograph.
The pharmaceutical product complaint was considered as unexpected by convention.
With reference to endotracheal tube obstruction, suspect pharmaceutical product complaint could provide an alternative explanation.
The company has assessed the causal relationship between Curosurf and endotracheal tube obstruction as conditional in accordance with the WHO-UMC causality assessment method.
With respect to pharmaceutical product complaint, investigational results are required for further assessment.
The company has assessed causal relationship between Curosurf and pharmaceutical product complaint as conditional as per convention.
The single individual case report does not modify the benefit / risk balance of this product. Therefore, no changes in the label or other measures are recommended at this point. However, the company will continue to monitor all respective reports received and based on cumulative experience, will re-evaluate the available evidence on an ongoing basis.