SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
UNKNOWN	CHINA	02	AUG	2025	1 Days	Female	1.50 kg	02	AUG	2025

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

BLOOD PRESSURE DECREASED [Blood pressure decreased]

Case Description: Case reference number 2025CHF05531 is a report sent by other health professional and received through regulatory authority (regulatory authority number: 5104011053941202500068) via Chinese affiliate (local country number: CC202508009) which refers to a neonate female patient aged 1 day (Han nationality).

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

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

#1) CUROSURF (PORACTANT ALFA) Endotracheopulmonary instillation, suspension, 80 milligram per millilitre {Lot #

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 240 milligram, QD	#1) Endotracheal

17. INDICATION(S) FOR USE

#1) NEONATAL RESPIRATORY DISTRE

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 02-AUG-2025 05:30:00 / 02-AUG-2025	#1) Unknown

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 to Ongoing	Current Condition	Premature baby (Premature baby)
Unknown to Ongoing	Current Condition	Neonatal pneumonia (Neonatal pneumonia)

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 #: CN-CHIESI-2025CHF05531

24b. MFR CONTROL NO.
2025CHF05531

24c. DATE RECEIVED BY MANUFACTURER
06-AUG-2025

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

DATE OF THIS REPORT
08-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER

CHINA

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient had no previous adverse drug reaction and the family adverse drug reaction history was unknown. The patient had no history of drug or food allergies in the past.

The patient was admitted to hospital on 02-Aug-2025 due to gestational age 32 + 4 weeks and foaming at mouth for 9 minutes after birth.

The patient’s admission diagnosis was neonatal respiratory distress syndrome, Neonatal pneumonia, Premature and low birth weight infant.

At around 5:10 in the morning, the patient's breathing became faster. There was progressive dyspnoea, and three concave signs was visible. Oxygen saturation was maintained under ventilator assisted ventilation. Considering the patient's condition, neonatal respiratory distress syndrome was obvious. After communicating with the family about the patient's condition, the family agreed to use porcine pulmonary surfactant.

On 02-Aug-2025, at 05:30, the patient was administered Curosurf [poractant alfa] (endotracheopulmonary instillation, suspension, 80 mg/ml, batch/lot no. 1209556, endotracheal) at a dose of 240 mg daily for neonatal respiratory distress syndrome.

On 02-Aug-2025, at 05:35, about 5 minutes after the use of porcine pulmonary surfactant, the patient experienced the life-threatening event of blood pressure decreased, periodic breathing, decreased reaction, pale skin, and crying after stimulation. Marble patterns were visible on the limbs. The capillary refill time of the patient was evaluated to be about 4 seconds. The patient's blood pressure was immediately monitored, which was considered that the child was allergic to porcine pulmonary surfactant.

Relevant laboratory and instrumental tests are shown in the relevant section.

The patient was treated for the event of blood pressure decreased with dexamethasone, IV and normal saline was given for volume expansion.

After intravenous injection of dexamethasone for about 15 minutes, the patient's complexion became more rosy than before, the marble pattern disappeared, the capillary refill time was less than 3 seconds, the reaction improved.

Suspected drug was withdrawn on 02-Aug-2025.

At the time of this report, the patient was recovering from the event.

The reporter considered the event as possible related to Curosurf.

No further information is expected as the report was received from health authority.

Case comments:
This 1 day-old female neonate experienced blood pressure decreased while being treated with Curosurf [poractant alfa] (endotracheopulmonary instillation, suspension, 80 mg/ml, batch/lot number: 1209556, endotracheal) at a dose of 240 mg daily for neonatal respiratory distress syndrome.
The event blood pressure decreased was assessed as serious (seriousness criterion: life-threatening).
The blood pressure decreased is not a listed adverse reaction for Curosurf according to reference safety information.
The adverse reaction of blood pressure decreased is unexpected as per US Prescribing Information.
The adverse reactions of blood pressure decreased is unexpected as per Canadian Product Monograph.
It was reported, about 5 minutes after the use of Curosurf, the patient's blood pressure was immediately monitored at 65/30 mmHg, which was considered that the child was allergic to Curosurf.
Regarding an event of blood pressure decreased, concurrent condition of prematurity could provide an alternative explanation, however, considering drug to event temporal association, a causal role of suspect drug cannot be denied.
The company has assessed the causal relationship between Curosurf and blood pressure decreased as possible in accordance with the WHO-UMC causality assessment method.
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.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	02-AUG-2025	Blood pressure measurement 65/30		
2	02-AUG-2025	Heart rate		

Mfr. Control Number: 2025CHF05531

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
3	02-AUG-2025	Oxygen saturation ABOVE 94 %		
4	02-AUG-2025	Respiratory rate 75-90 times/min		
5	02-AUG-2025	Respiratory rate 55-77 times/min		

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) CUROSURF (PORACTANT ALFA) Endotracheopulmonary instillation, suspension, 80 milligram per millilitre {Lot # 1209556}; Regimen #1	240 milligram, QD; Endotracheal	NEONATAL RESPIRATORY DISTRESS SYNDROME (Neonatal respiratory distress syndrome)	02-AUG-2025 05:30:00 / 02-AUG-2025; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Low birth weight baby (Low birth weight baby);