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	CHINA	28	MAY	2025	Unk	Female	1.20 kg	31	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
TACHYCARDIA [Neonatal tachycardia]

Case Description: Case reference number 2025CHF04084 is a report sent by other health professional and received through health authority (health authority report number: 330784106196720250003 9) via Chinese affiliate (local country number: CC202506001) which refers to a neonate female patient (Han nationality).

(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) PEYONA (CAFFEINE CITRATE) Solution for infusion and oral solution, 20 milligram per millilitre {Lot # 25915}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 12 milligram, QD

16. ROUTE(S) OF ADMINISTRATION
#1) Other

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)
#1) 31-MAY-2025 / 31-MAY-2025

19. THERAPY DURATION
#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Glucose (Glucose) Injection, 5 percent; 31-MAY-2025 / 31-MAY-2025

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 #: CN-CHIESI-2025CHF04084

24b. MFR CONTROL NO.
2025CHF04084

25b. NAME AND ADDRESS OF REPORTER

CHINA

24c. DATE RECEIVED BY MANUFACTURER
05-JUN-2025

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

DATE OF THIS REPORT
19-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Concomitant medications and past drug history have not been provided.

The patient had no previous adverse drug reaction and family adverse drug reaction history.

On 31-May-2025, the patient started taking Peyona [caffeine citrate] (Solution for infusion and oral solution, 20 milligram per millilitre, batch number: 25915, other: in-pump injection) at 12 mg daily for neonatal respiratory distress.

The patient was also under treatment with glucose (injection, 5 %, batch number: E24121406) at 2 ml daily for solvent (medication dilution) (on 31-May-2025).

On 31-May-2025, the patient developed significant medical event of tachycardia (neonatal tachycardia).

The event of neonatal tachycardia was considered as serious as it is included in the EMA IME list.

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

Suspected drug was withdrawn on 31-May-2025.

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

The reporter considered the event probably related to Clenil.

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

Case comments:
This female neonate experienced “tachycardia” (neonatal tachycardia) while being treated with Peyona [caffeine citrate] (Solution for infusion and oral solution, 20 milligram per milliliter, batch number: 25915, other: in-pump injection) at 12 mg daily for neonatal respiratory distress.
The event “tachycardia” was assessed as serious (seriousness criterion: important medical event).
The event of neonatal tachycardia was considered as serious as it is included in the EMA IME list.
The neonatal tachycardia is a listed adverse reaction for Peyona according to the reference safety information.
The adverse reaction of neonatal tachycardia is expected as per Canadian Product Monograph.
It was reported that, after medication for half an hour, the patient developed heart rate increased from 150 times/min to 175 times/min. Then the medication was stopped immediately. The patient recovered to 155 times/min the next day.
With respect to neonatal tachycardia, underlying condition of neonatal respiratory distress could provide an alternative explanation, however, considering drug to event temporal relationship, known safety profile and event was recovering after withdrawal of suspect drug, the causal role of Peyona seems likely.
The company has assessed causal relationship between Peyona and neonatal tachycardia as probably related 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	31-MAY-2025	Heart rate	150 heart beats per minute	
2	31-MAY-2025	Heart rate	175 heart beats per minute	
3	01-JUN-2025	Heart rate	155 heart beats per minute	

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) PEYONA (CAFFEINE CITRATE) Solution for infusion and oral solution, 20 milligram per millilitre {Lot # 25915}; Regimen #1	12 milligram, QD; Other	NEONATAL RESPIRATORY DISTRESS (Neonatal respiratory distress)	31-MAY-2025 / 31-MAY-2025; Unknown