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
PRIVACY	COSTA RICA		PRIVACY		11 Months	Female	Unk	06	AUG	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Fiebre [Pyrexia]	PALIVIZUMAB	No	Yes	Not Applicable	Related
Gripe [Influenza]	PALIVIZUMAB	No	No	Not Applicable	Related

(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) PALIVIZUMAB (PALIVIZUMAB) Injection
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) UNK

16. ROUTE(S) OF ADMINISTRATION
#1) Intramuscular use

17. INDICATION(S) FOR USE
#1) Respiratory Syncytial Virus (Respirat
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 09-JUL-2025 / Ongoing

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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown	Indication	
Unknown	Indication	

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: CR-ASTRAZENECA-202508CAM010529CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00931259A

24b. MFR CONTROL NO.
202508CAM010529CR

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
18-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202508CAM010529CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female infant patient born in 2024 (age 11 months).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Palivizumab (palivizumab) UNK, Intramuscular use, on 09-JUL-2025 for respiratory syncytial virus.

On 06-AUG-25, the patient experienced fiebre (preferred term: Pyrexia). On an unknown date, the patient experienced gripe (preferred term: Influenza).

The dose of Palivizumab (palivizumab) was not changed.

The patient recovered from the event(s) fiebre and gripe on an unspecified date.

The events were considered non-serious.

The reporter did not assess causality for fiebre and gripe.
The company physician considered that there was a reasonable possibility of a causal relationship between Palivizumab and the following event(s): fiebre and gripe.

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) PALIVIZUMAB (PALIVIZUMAB) Injection; Regimen #1	UNK; Intramuscular use	Respiratory Syncytial Virus (Respiratory syncytial virus infection)	09-JUL-2025 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Indication	Respiratory syncytial virus infection (Respiratory syncytial virus infection);
Unknown	Indication	Respiratory syncytial virus infection NOS (Respiratory syncytial virus infection);