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	GUATEMALA		PRIVACY		Unk	Male	Unk		Unk	

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
Gripe [Influenza]	SYNAGIS	No	No	Not Related	Not Related
Uso Off-Label [Off label use]	SYNAGIS	No	No	Not Related	Not Applicable

(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) SYNAGIS (PALIVIZUMAB) Injection {Lot # Unknown}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) Unknown

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

17. INDICATION(S) FOR USE
#1) Premature (Premature baby)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 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	Birth weight low (Low birth weight baby)
Unknown	Indication	Premature baby (Premature baby)

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 #: GT-ASTRAZENECA-202507CAM010232GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00910323A

24b. MFR CONTROL NO.
202507CAM010232GT

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
17-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202507CAM010232GT

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 male patient born in 2025.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Synagis (palivizumab) (batch number(s) Unknown) 100 milligram per millilitre qmonth, Intramuscular use, on an unknown date for and low weight and premature.

On an unknown date, the patient experienced uso off-label (preferred term: Off label use) and gripe (preferred term: Influenza).

The dose of Synagis (palivizumab) was not changed.

The patient recovered from the event(s) gripe on an unspecified date. The outcome of the event(s) of uso off-label was unknown.

The events were considered non-serious.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Synagis and the following event (s): gripe and uso off-label.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Synagis and the following event(s): 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) SYNAGIS (PALIVIZUMAB) Injection {Lot # Unknown}; Regimen #1	Unknown; Intramuscular use	Premature (Premature baby) and low weight (Low birth weight baby)	Ongoing; Unknown