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
PRIVACY	COSTA RICA		PRIVACY		41 Years	Female	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
Iron deficiency [Iron deficiency]	ANIFROLUMAB	No	No	Not Applicable	Not Related
dry skin [Dry skin]	ANIFROLUMAB	No	No	Not Applicable	Not Related
pimples on the arms [Dermatitis acneiform]	ANIFROLUMAB	No	No	Not Applicable	Not 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) ANIFROLUMAB (ANIFROLUMAB) Solution for injection

15. DAILY DOSE(S)
#1) 300 milligram, q4w

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

17. INDICATION(S) FOR USE
#1) Lupus (Systemic lupus erythematosus)

18. THERAPY DATES(from/to)
#1) 27-MAY-2025 / Ongoing

19. THERAPY DURATION
#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 to Ongoing	Indication	Lupus syndrome (Systemic lupus erythematosus)

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-202508CAM018233CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00936684A

24b. MFR CONTROL NO.
202508CAM018233CR

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

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

DATE OF THIS REPORT
27-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

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 adult patient born in 1984 (age 41 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Anifrolumab (anifrolumab) 300 milligram q4w, Intravenous use, on 27-MAY-2025 for lupus.

On an unknown date, the patient experienced dry skin (preferred term: Dry skin), iron deficiency (preferred term: Iron deficiency) and pimples on the arms (preferred term: Dermatitis acneiform).

The dose of Anifrolumab (anifrolumab) was not changed.

At the time of reporting, the event dry skin, iron deficiency and pimples on the arms was ongoing.

The events were considered non-serious.

The reporter did not assess causality for dry skin, iron deficiency and pimples on the arms.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Anifrolumab and the following event(s): dry skin, iron deficiency and pimples on the arms.