

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year				Day	Month	Year	
			PRIVACY		Unk	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
Tiredness [Fatigue]	SAPHNELO	No	No	Related	Related
Headache [Headache]	SAPHNELO	No	No	Related	Related

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) SAPHNELO (ANIFROLUMAB) Solution for injection		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
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)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 14-AUG-2024 / 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 Unknown to Ongoing	Type of History / Notes Indication	Description 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-202504CAM027950CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00861304A
	24b. MFR CONTROL NO. 202504CAM027950CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 30-APR-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 06-MAY-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

06-May-2025 03:38

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 patient born in 1978.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Saphnelo (anifrolumab) 300 milligram q4w, Intravenous use, on 14-AUG-2024 for lupus.

On an unknown date, the patient experienced headache (preferred term: Headache) and tiredness (preferred term: Fatigue).

The dose of Saphnelo (anifrolumab) was not changed.

The patient recovered from the event(s) headache and tiredness on an unspecified date.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): headache and tiredness.

The company physician considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): headache and tiredness.