

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH			2a. AGE 29 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
			PRIVACY					18	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
Nauseas [Nausea]	SAPHNELO	No	No	Related	Related
Dolor de cabeza [Headache]	SAPHNELO	No	No	Related	Related
I got a bit dizzy [Dizziness]	SAPHNELO	No	No	Related	Related

(Continued on Additional Information Page)

☐ 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) 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 (Antiphospholipid antibodies)		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-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 Unknown to Ongoing Unknown	Type of History / Notes Indication Indication	Description Lupus anticoagulant (Antiphospholipid antibodies) Antiphospholipid antibodies (Antiphospholipid antibodies)

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-202508CAM013128GT Study ID: PSP- 23269 Case References: GT-AstraZeneca-CH-00932907A
	24b. MFR CONTROL NO. 202508CAM013128GT	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 18-AUG-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 20-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

20-Aug-2025 14:18

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 of Hispanic ethnic origin born in 1996 (age 29 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Saphnelo (anifrolumab) 300 milligram q4w, Intravenous use, on 14-JUL-2025 for lupus.

On 18-AUG-25, the patient experienced nauseas (preferred term: Nausea), i got a bit dizzy (preferred term: Dizziness) and dolor de cabeza (preferred term: Headache).

The dose of Saphnelo (anifrolumab) was not changed.

The patient recovered from the event(s) dolor de cabeza, i got a bit dizzy and nauseas after 1 day on 18-AUG-2025.

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): dolor de cabeza, i got a bit dizzy and nauseas.

The company physician considered that there was a reasonable possibility of a causal relationship between Saphnelo and the following event(s): dolor de cabeza, i got a bit dizzy and nauseas.