

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
		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
Cansancio [Fatigue]	ACALABRUTINIB	No	Yes	Related	Related
Cosa rarísima en el brazo [Limb injury]	ACALABRUTINIB	No	No	Related	Related
Piernas hinchadas [Peripheral swelling]	ACALABRUTINIB	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) ACALABRUTINIB (ACALABRUTINIB) Film-coated tablet		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 100 milligram, q12h	16. ROUTE(S) OF ADMINISTRATION #1) Oral use	
17. INDICATION(S) FOR USE #1) LLC (Chronic lymphocytic leukaemia)		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-MAR-2025 / Unknown	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 to Ongoing 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-202507CAM026517CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00921872A
	24b. MFR CONTROL NO. 202507CAM026517CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 30-JUL-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 01-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

01-Aug-2025 10:03

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 1942.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Acalabrutinib (acalabrutinib) 100 milligram q12h, Oral use, on 14-MAR-2025 for Ilc.

On an unknown date, the patient experienced cansancio (preferred term: Fatigue), piernas hinchadas (preferred term: Peripheral swelling) and cosa rarísima en el brazo (preferred term: Limb injury).

The dose of Acalabrutinib was reduced.

At the time of reporting, the event cansancio, cosa rarísima en el brazo and piernas hinchadas was improving.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event (s): cansancio, cosa rarísima en el brazo and piernas hinchadas.

The company physician considered that there was a reasonable possibility of a causal relationship between Acalabrutinib and the following event(s): cansancio, cosa rarísima en el brazo and piernas hinchadas.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Indication	Chronic lymphocytic leukaemia (Chronic lymphocytic leukaemia);