**CIOMS FORM**

# 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 | COSTA RICA | | 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 |
|---|---|---|---|---|---|
| Edema podálico [Oedema peripheral] | CALQUENCE | No | No | Related | |
| Diarrea [Diarrhoea] | CALQUENCE | No | Yes | | |

**(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 ) CALQUENCE (ACALABRUTINIB) Film-coated tablet

15. DAILY DOSE(S)
#1 ) 100 milligram, qd

16. ROUTE(S) OF ADMINISTRATION
#1 ) Unknown

17. INDICATION(S) FOR USE
#1 ) unk (Product used for unknown indication)

18. THERAPY DATES(from/to)
#1 ) Unknown

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 | 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-202507CAM016961CR
Case References: CR-AstraZeneca-CH-00915063A

24b. MFR CONTROL NO.
**202507CAM016961CR**

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

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

DATE OF THIS REPORT
23-JUL-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 spontaneous report has been received from a physician. The report concerns a female patient (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Calquence (acalabrutinib) 100 milligram qd, on an unknown date for unk.

On an unknown date, the patient experienced edema podálico (preferred term: Oedema peripheral) and diarrea (preferred term: Diarrhoea).

Treatment with Calquence (acalabrutinib) was temporarily Withdrawn.

The outcome of the event(s) of diarrea and edema podálico was unknown.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Calquence and the following event (s): edema podálico.

**23. OTHER RELEVANT HISTORY continued**

| From/To Dates | Type of History / Notes | Description |
|---|---|---|
| Unknown | Indication | Product used for unknown indication (Product used for unknown indication); |