**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 | | 81 Years | Female | Unk | 01 | JUL | 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 |
|---|---|---|---|---|---|
| PATIENT WITH STOMACH PAIN [Abdominal pain upper] | DAPAGLIFLOZIN | No | No | Not Applicable | Related |
| PATIENT BECAME ILL [Illness] | DAPAGLIFLOZIN | No | No | Not Applicable | Related |
| PATIENT WITH LUNG PROBLEMS. [Lung disorder] | DAPAGLIFLOZIN | No | No | Not Applicable | 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 ) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet

15. DAILY DOSE(S)
#1 ) 10 milligram

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

17. INDICATION(S) FOR USE
#1 ) (Not Coded)

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

## 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-202507CAM000344CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00902248A

24b. MFR CONTROL NO.
**202507CAM000344CR**

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

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

DATE OF THIS REPORT
03-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 solicited report has been received from a consumer in Patient Support Program. The report concerns a female elderly patient born in 1943 (age 81 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin (dapagliflozin) 10 milligram, Oral use, on an unknown date.

On 01-JUL-25, the patient experienced patient with stomach pain (preferred term: Abdominal pain upper) and patient became ill (preferred term: Illness). On an unknown date, the patient experienced patient with lung problems. (preferred term: Lung disorder).

It is unknown if any action was taken with Dapagliflozin (dapagliflozin).

The outcome of the event(s) of patient became ill, patient with lung problems. and patient with stomach pain was unknown.

The events were considered non-serious.

The reporter did not assess causality for patient became ill, patient with lung problems. and patient with stomach pain.
The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): patient became ill, patient with lung problems. and patient with stomach pain.