**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 | Male | 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 |
|---|---|---|---|---|---|
| Chest pain [Chest pain] | FORXIGA | Yes | No | Not Related | Not Related |
| PATIENT TAKES FORXIGA 10MG FOR A HEART ATTACK [Off label use] | FORXIGA | No | No | Not Related | Not Applicable |

**(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 ) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # PTO170; Exp.Dt. DEC-2026}

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

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

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

17. INDICATION(S) FOR USE
#1 ) Infarction (Infarction)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)
#1 ) 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 | Historical Condition | Chest pain (Chest pain) |
| Unknown to Ongoing | Indication | Infarction (Infarction) |

## 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-202507CAM019631CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00916972A

24b. MFR CONTROL NO.
**202507CAM019631CR**

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
24-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

## 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 male patient born in 1953.

The patient’s past and current medical history included chest pain (dates not reported).

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) PTO170) (expiration date(s) DEC-2026) 10 milligram qd, Oral use, on an unknown date for infarction.

On an unknown date, the patient experienced chest pain (preferred term: Chest pain) and patient takes forxiga 10mg for a heart attack (preferred term: Off label use).

The report described off-label use for Forxiga. The reported term was patient takes forxiga 10mg for a heart attack (preferred term: Off label use).

The outcome of the event(s) of patient takes forxiga 10mg for a heart attack was unknown. At the time of reporting, the event chest pain was improving.

The following event(s) were considered serious due to hospitalized:chest pain.

The following event was considered non-serious:patient takes forxiga 10mg for a heart attack.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event (s): chest pain and patient takes forxiga 10mg for a heart attack.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): chest pain.