**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 |
|---|---|---|---|---|---|
| Vaginal itching [Vulvovaginal pruritus] | FORXIGA | No | No | Related | Related |
| Sugar is rising [Blood glucose increased] | FORXIGA | No | No | Related | Related |
| Forget things [Memory impairment] | FORXIGA | No | No | Unknown | Unknown |
| Weight loss [Weight decreased] | FORXIGA | No | No | Related | Related |
| Urinates sugar [Glucose urine] | FORXIGA | No | No | Related | 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 ) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # WM0090; Exp.Dt. APR-2027}

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

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

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

18. THERAPY DATES(from/to)
#1 ) 2013 / Ongoing

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 to Ongoing | Indication | Diabetes (Diabetes mellitus) |

## 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-202505CAM016309CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00874218AM

24b. MFR CONTROL NO.
**202505CAM016309CR**

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
20-MAY-2025

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

DATE OF THIS REPORT
23-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

## ADDITIONAL INFORMATION

**7+13. DESCRIBE REACTION(S) continued**

Case Description: A solicited report has been received from a non-health professional in Patient Support Program. The report concerns a female patient (age not provided).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) WM0090) (expiration date(s) APR-2027) 10 milligram qd, Oral use, during 2013.

On an unknown date, the patient experienced vaginal itching (preferred term: Vulvovaginal pruritus), urinates sugar (preferred term: Glucose urine), weight loss (preferred term: Weight decreased), forget things (preferred term: Memory impairment) and sugar is rising (preferred term: Blood glucose increased).

The dose of Forxiga (dapagliflozin) was not changed.

The outcome of the event(s) of forget things, sugar is rising, urinates sugar, vaginal itching and weight loss was unknown.

The events were considered non-serious.

The reporter did not assess causality for forget things.The reporter considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): sugar is rising, urinates sugar, vaginal itching and weight loss.
The company physician considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): sugar is rising, urinates sugar, vaginal itching and weight loss.