# 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)

Other Serious Criteria: Medically Significant

| Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) | Product | Serious | Listed | Reporter Causality | Company Causality |
|---|---|---|---|---|---|
| Medication did not regulate his sugar [Diabetes mellitus inadequate control] | DAPAGLIFLOZIN | Yes | No | Related | Not Related |
| Medication did not regulate his sugar [Diabetes mellitus inadequate control] | XIGDUO | Yes | No | Not Applicable | Not 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
#2 ) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet

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

15. DAILY DOSE(S)
#1 ) 10 milligram, qid
#2 ) UNK

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

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

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

18. THERAPY DATES(from/to)
#1 ) 2025 / Unknown
#2 ) Ongoing

19. THERAPY DURATION
#1 ) Unknown
#2 ) 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 | 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-202506CAM022053CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00898567A

24b. MFR CONTROL NO.
**202506CAM022053CR**

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
25-JUN-2025

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

DATE OF THIS REPORT
02-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 (age not provided).

No medical history and concomitant products were reported.

On an unknown date, the patient started treatment with Dapagliflozin (dapagliflozin) 10 milligram qid, Oral use, during 2025 for diabetes and with Xigduo (dapagliflozin, metformin) UNK.

On an unknown date, the patient experienced medication did not regulate his sugar (preferred term: Diabetes mellitus inadequate control).

The dose of Xigduo (dapagliflozin, metformin) was not changed.

The patient recovered from the event(s) medication did not regulate his sugar on an unspecified date.

The Company assessed event medication did not regulate his sugar as serious due to seriousness criteria of Medically Significant.

The reporter did not assess causality for medication did not regulate his sugar.The reporter considered that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): medication did not regulate his sugar.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): medication did not regulate his sugar.  The company physician did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): medication did not regulate his sugar.

Company Clinical Comment: Diabetes mellitus inadequate control is not listed in the company core data sheet of dapagliflozin. Underlying diabetes mellitus could be a possible contributory risk factor for the occurrence of event. Due to limited information on complete patient demographics, start date of suspect drug, circumstances leading to event, event onset date, clinical course, treatment provided, risk factors, relevant medical history, concurrent conditions, concomitant medications, detailed diagnostic and etiologic workup, the evaluation did not find the evidence to suggest a causal relationship between the event and suspect drug.