# 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 |
|---|---|---|---|---|---|
| Blood sugar was rising [Blood glucose increased] | XIGDUO | No | No | Not Applicable | Not Related |
| very strong diarrhea [Diarrhoea] | XIGDUO | No | Yes | Related | Related |
| Medication didnt work (lack of efficacy) [Drug ineffective] | XIGDUO | No | No | Related | Not Related |
| Xigduo 5mg/1000mg 2 times a day (off-label) [Off label use] | XIGDUO | No | No | Not Applicable | 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 ) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # Unknown}
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1 ) 5 milligram, qd

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

17. INDICATION(S) FOR USE
#1 ) Diabetes (Diabetes mellitus)

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 to Ongoing | Indication | Diabetes (Diabetes) |
| Unknown | Historical Condition | Diarrhea (Diarrhoea) |

## 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-202508CAM001438CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00924257A

24b. MFR CONTROL NO.
**202508CAM001438CR**

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
04-AUG-2025

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

DATE OF THIS REPORT
08-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202508CAM001438CR

## 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 patient born in 1932.

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

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) (batch number(s) Unknown) 5 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced medication didnt work (lack of efficacy) (preferred term: Drug ineffective), blood sugar was rising (preferred term: Blood glucose increased), severe very strong diarrhea (preferred term: Diarrhoea) and xigduo 5mg/1000mg 2 times a day (off-label) (preferred term: Off label use).

The report described off-label use for Xigduo. The reported term was xigduo 5mg/1000mg 2 times a day (off-label) (preferred term: Off label use). The report described lack of effect for Xigduo. The reported term was "medication didnt work (lack of efficacy)" (preferred term: Drug ineffective).

Treatment with Xigduo (dapagliflozin, metformin) was discontinued during 2025.

The outcome of the event(s) of medication didnt work (lack of efficacy) and xigduo 5mg/1000mg 2 times a day (off-label) was unknown. At the time of reporting, the event blood sugar was rising and very strong diarrhea was ongoing.

The events were considered non-serious.

The reporter did not assess causality for blood sugar was rising and xigduo 5mg/1000mg 2 times a day (off-label).The reporter considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): medication didnt work (lack of efficacy) and very strong diarrhea.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): blood sugar was rising and medication didnt work (lack of efficacy). The company physician considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): very strong diarrhea.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet; Regimen #2 | 5 milligram, bid; Oral use | Diabetes (Diabetes mellitus) | Unknown / 2025; Unknown |