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	GUATEMALA		PRIVACY		39 Years	Male	Unk	08	MAR	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
Vómitos [Vomiting]	XIGDUO	No	Yes	Related	Related
Adormeciiento en brazos y piernas [Hypoaesthesia]	XIGDUO	No	No	Related	Related
Adormecimiento en lengua [Hypoaesthesia oral]	XIGDUO	No	No	Related	Related
Diarrea muy fuerte [Diarrhoea]	XIGDUO	No	Yes	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) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # Unknown}

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

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

17. INDICATION(S) FOR USE
#1) Type 2 Diabetes (Type 2 diabetes mellitus)

18. THERAPY DATES(from/to)
#1) 08-MAR-2025 / 13-MAR-2025

19. THERAPY DURATION
#1) 6 days

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	Type II diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Indication	Type 2 diabetes mellitus (Type 2 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 #: GT-ASTRAZENECA-202505CAM003462GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00864232A

24b. MFR CONTROL NO.
202505CAM003462GT

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

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

DATE OF THIS REPORT
07-MAY-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 male adult patient born in 1985 (age 39 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Xigduo (dapagliflozin, metformin) (batch number(s) Unknown) 5 milligram qd, Oral use, on 08-MAR-2025 for type 2 diabetes.

On 08-MAR-25, the patient experienced vómitos (preferred term: Vomiting), diarrea muy fuerte (preferred term: Diarrhoea), adormecimiento en lengua (preferred term: Hypoaesthesia oral) and adormeciiento en brazos y piernas (preferred term: Hypoaesthesia).
The last dose of XIGDUO prior to onset was taken on 13-MAR-25.

Treatment with Xigduo (dapagliflozin, metformin) was discontinued on 13-MAR-2025.

The patient recovered from the event(s) adormeciiento en brazos y piernas, adormecimiento en lengua and vómitos after 6 days on 14-MAR-2025. The patient recovered from the event(s) diarrea muy fuerte after 15 days on 23-MAR-2025.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): adormeciiento en brazos y piernas, adormecimiento en lengua, diarrea muy fuerte and vómitos.
The company physician considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): adormeciiento en brazos y piernas, adormecimiento en lengua, diarrea muy fuerte and vómitos.

Laboratory values are available.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood potassium UNK		