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		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
Infección (no especifica) [Infection]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Related
Dos pastillas de Forxiga 10 mg al día (uso no aprobado) [Off label use]	DAPAGLIFLOZIN	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) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet

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

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

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

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

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 #: GT-ASTRAZENECA-202504CAM026041GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00859558A

24b. MFR CONTROL NO.
202504CAM026041GT

24c. DATE RECEIVED BY MANUFACTURER
29-APR-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 female patient born in 1955.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin (dapagliflozin) 10 milligram bid, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced infección (no especifica) (preferred term: Infection) and dos pastillas de forxiga 10 mg al día (uso no aprobado) (preferred term: Off label use).

The patient recovered from the event(s) infección (no especifica) on an unspecified date. The outcome of the event(s) of dos pastillas de forxiga 10 mg al día (uso no aprobado) was unknown.

The events were considered non-serious.

The reporter did not assess causality for dos pastillas de forxiga 10 mg al día (uso no aprobado) and infección (no especifica).
The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): infección (no especifica).