SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		78 Years	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
Eye hemorrhage [Eye haemorrhage]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Related	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, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # wf0211; Exp.Dt. APR-2026}

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

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

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

17. INDICATION(S) FOR USE
#1) For the sugar (Blood glucose abnormal)

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	Glucose abnormal (Blood glucose abnormal)
Unknown	Indication	Blood glucose abnormal (Blood glucose abnormal)

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-202505CAM025420CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00880710A

24b. MFR CONTROL NO.
202505CAM025420CR

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
03-JUN-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 female elderly patient born in 1947 (age 78 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) (batch number(s) wf0211) (expiration date(s) APR-2026) 10 milligram qd, Oral use, on an unknown date for for the sugar.

On an unknown date, the patient experienced eye hemorrhage (preferred term: Eye haemorrhage).

It is unknown if any action was taken with Dapagliflozin, Metformin (dapagliflozin, metformin).

The outcome of the event(s) of eye hemorrhage was unknown.

The event was considered non-serious.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): eye hemorrhage.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): eye hemorrhage.