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
Stroke [Cerebrovascular accident]	DAPAGLIFLOZIN	Yes	No	Not Related	Not Related
Stroke [Cerebrovascular accident]	ATACAND	Yes	No	Not Applicable	Not Related
Stroke [Cerebrovascular accident]	CRESTOR	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 {Lot # WH0134; Exp.Dt. OCT-2026}

#2) ATACAND (CANDESARTAN CILEXETIL) Tablet {Lot # 80171; Exp.Dt. **(Continued on Additional Information Page)**

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

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

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

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

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

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

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	Historical Condition	Blood pressure (Blood pressure measurement)
Unknown	Historical Condition	Cardiac arrhythmia (Arrhythmia)

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-202505CAM024524CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00880080A

24b. MFR CONTROL NO.
202505CAM024524CR

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
01-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 concerning a male patient born in 1960.

The patient's past and current medical history included blood pressure (dates not reported), cardiac arrhythmia (dates not reported), diabetes (dates not reported) and stroke (dates not reported).

No concomitant products were reported.

On an unknown date, the patient started treatment with Atacand (candesartan cilexetil) (batch number(s) 80171) (expiration date(s) Apr-2026) 32 milligram qd, Oral use, for blood pressure, with Crestor (rosuvastatin) (batch number(s) 80803) (expiration date(s) Jul-2026) 20 milligram qd, Oral use, on an unknown date for cardiac arrhythmia and with Dapagliflozin (dapagliflozin) (batch number (s) WH0134) (expiration date(s) OCT-2026) 10 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient was experienced stroke (preferred term: Cerebrovascular accident).

At the time of reporting, the event stroke was improving.

The reporter assessed event stroke was considered serious due to medically significant.

The reporter did not assess causality for stroke.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): stroke.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Atacand and the following event(s): stroke. The company physician did not consider that there was a reasonable possibility of a causal relationship between Crestor and the following event(s): stroke. The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): stroke.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#2) ATACAND (CANDESARTAN CILEXETIL) Tablet {Lot # 80171; Exp.Dt. APR-2026}; Regimen #1	Unknown; Oral use	Blood pressure (Blood pressure)	Unknown; Unknown
#3) CRESTOR (ROSUVASTATIN) Film-coated tablet {Lot # 80803; Exp.Dt. JUL-2026}; Regimen #1	Unknown; Oral use	Cardiac Arrhythmia (Arrhythmia)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Stroke (Cerebrovascular accident);
Unknown to Ongoing	Indication	Blood pressure (Blood pressure);
Unknown to Ongoing	Indication	Diabetes (Diabetes);
Unknown	Historical Condition	Diabetes (Diabetes mellitus);
Unknown	Indication	Cardiac arrhythmia (Arrhythmia);