# SUSPECT ADVERSE REACTION REPORT

MFR. CONTROL NO.: **2025006843-000**



I. REACTION INFORMATION

| 1. PATIENT INITIALS | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE | 3. SEX | 4.-6. REACTION ONSET | | | 8.-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|
| | | DAY | MONTH | YEAR | | | DAY | MONTH | YEAR | |
| UNK | CR | 18 | Oct | 1960 | | M | | | | ☐ PATIENT DIED<br>☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION<br>☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY<br>☐ LIFE THREATENING<br>☐ CONGENITAL ANOMALY OR BIRTH DEFECT<br>☒ OTHER MEDICALLY IMPORTANT CONDITION |

7. - 13. DESCRIBE REACTION(S) (including relevant tests/lab data) — REACTION ONSET

1. Stroke

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

1. Candesartan (CANDESARTAN CILEXETIL)
2. Dapagliflozin (DAPAGLIFLOZIN)

20. DID EVENT ABATE AFTER STOPPING DRUG?

☐ YES ☐ NO ☐ NA ☐ UNK

| 15. DAILY DOSE | 16. ROUTE OF ADMINISTRATION | 21. DID EVENT REAPPEAR AFTER REINTRODUCTION? |
|---|---|---|
| 1. 32 Milligram | 1. Oral use | ☐ YES ☐ NO ☐ NA ☐ UNK |
| 2. 10 Milligram | 2. Oral use | |

17. INDICATION(S) FOR USE

1. Blood pressure
2. Diabetes

| 18. THERAPY DATES (from / to) | 19. THERAPY DURATION (=latency) |
|---|---|
| 1. / | 1. |
| 2. / | 2. |

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (exclude those used to treat event) — Therapy Dates (from / to)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period etc.)

Current disease / condition

1. Blood pressure
2. Cardiac arrhythmia
3. Diabetes

IV. MANUFACTURER

24a. NAME AND ADDRESS OF MANUFACTURER

CHEPLAPHARM Arzneimittel GmbH
Ziegelhof 24
17489 Greifswald
Germany

24b. MFR. CONTROL NO.

2025006843-000

| 24c. DATE RECEIVED BY MANUFACTURER | 24d. REPORT SOURCE |
|---|---|
| 01-Jun-2025 | ☐ STUDY ☐ LITERATURE ☒ OTHER<br>☐ HEALTH PROFESSIONAL ☒ CONSUMER |
| DATE OF THIS REPORT | 25a. REPORT TYPE |
| 06-Jun-2025 | ☒ INITIAL ☐ FOLLOW-UP ☐ FINAL |

**ATTACHMENT 7.-13. Describe reactions**

1. (Reported term): Stroke
   (Term as per company): Stroke
   (LLT / Code // PT / Code of MedDRA version 28.0): Stroke / 10042244 // Cerebrovascular accident / 10008190
   (Seriousness as per reporter // as per company): Serious // Serious
   (Seriousness criteria as per reporter // as per company): Other medically important condition // Other medically important condition
   (Outcome as per reporter // as per company): Recovering / resolving //

(AE description):

This Spontaneous, NOS case, initially reported by a Consumer or other non health professional was received on 01-Jun-2025 from divestment partner AstraZeneca (CR-ASTRAZENECA-202505CAM024524CR) and concerns an adult Male patient of unspecified age who was treated with candesartan cilexetil (Atacand), dapagliflozin, rosuvastatin, and experienced Stroke.

Medical History: Blood pressure management, Cardiac arrhythmia, Diabetes and Stroke

Initial narrative provided:
[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.]

Changes made by CHEPLAPHARM:
- Captured age group based on reported date of birth in the absence of event onset dates.

**ATTACHMENT 14. Suspect drugs**

1. (Drug name / Substance): Candesartan / CANDESARTAN CILEXETIL
   (Indication for use - Reported term): Blood pressure
   (Additional information on drug): reported as Atacand
   1. Therapy data:
      (Galenical form // Route of administration): Tablet // Oral use
      (Dose // Daily dose): x 32 Milligram in 1 Day // 32 Milligram
   1. Approval data:
      (Type of authorisation): Valid

   Labelling data:
      (AE reported term): Stroke
      (Country / Labelled/Expected/Listed): CCDS / No
   1. Causality data:
      (AE reported term): Stroke
      (Causality as per reporter // as per company): Not reported // No reasonable possibility
2. (Drug name / Substance): Dapagliflozin / DAPAGLIFLOZIN
   (Indication for use - Reported term): Diabetes
   1. Therapy data:
      (Galenical form // Route of administration): Film-coated tablet // Oral use

(Dose // Daily dose): x 10 Milligram in 1 Day // 10 Milligram
(Dosage information): 10 milligram, qd

3. (Drug name / Substance): Crestor / ROSUVASTATIN
(Indication for use - Reported term): Cardiac arrhythmia
1. Therapy data:
(Galenical form // Route of administration): Film-coated tablet // Oral use
(Dose // Daily dose): x 20 Milligram in 1 Day // 20 Milligram

**ATTACHMENT 23. Other relevant history**

Current disease/condition:

1. (Reported term): Blood pressure
(LLT / Code of MedDRA version 28.0): Blood pressure management / 10063926
2. (Reported term): Cardiac arrhythmia
(LLT / Code of MedDRA version 28.0): Cardiac arrhythmia / 10007518
3. (Reported term): Diabetes
(LLT / Code of MedDRA version 28.0): Diabetes / 10012594

Past history:

1. (Reported term): Stroke
(LLT / Code of MedDRA version 28.0): Stroke / 10042244

Medical episode unstructured:
unk

**Patient data**

(Initials): UNK
(Sex): M
(Date of birth): 18-Oct-1960
(Age group): Adult

**Assessment**

1. (Version date): 05-Jun-2025
(Assessment type): Assessment as per company
(English): Cerebrovascular accident, (Stroke) is not listed for CANDESARTAN CILEXETIL (CCDS).

The benefit/risk profile of the product remains unaffected; case closed; no further information is expected.

Considering the known safety profile of the drug, there is no reasonable possibility for the suspect drug to cause the event. The event can be explained by underlying condition of the patient or use of Dapagliflozin.

**References**

1. (Reference number): 2025CP06965
(Reference owner // Reference type): CHEPLAPHARM // Additional internal number for this case

2. (Reference number): CR-ASTRAZENECA-202505CAM024524CR
(Reference owner // Reference type): AstraZeneca // Worldwide ref. number alloc. by other company

3. (Reference number): CR-AstraZeneca-CH-00880080A
(Reference owner // Reference type): AstraZeneca // Other reference

4. (Reference number): CR-CHEPLA-2025006843
(Reference owner // Reference type): CHEPLAPHARM // Other reference