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		89 Years	Male	80.00 kg		MAR	2024

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Medically Significant
Death [Death NOS]
Cerebrovascular accident [Cerebrovascular accident]
Weight loss [Weight loss]

Case Description: This spontaneous case was received from a Consumer in COSTA RICA.

The patient was a 89 years-old male (weight: 80kg; height: 183cm) with a medical history of Blood purification since an unknown date, treated with

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: MAR-2024
- ☐ 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) DAFLON 1000mg Comprimidos Recubierto con Pelicula (PURIFIED FLAVONOID FRACTION 1000 mg)
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1000 mg, qd	#1) Oral use

17. INDICATION(S) FOR USE
#1) Blood purification (Blood disorder)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2019 / MAR-2024	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Lantus (Insulin glargine) ; Unknown

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

From/To Dates	Type of History / Notes	Description
1980 to Ongoing	Historical Condition	Hypertension (Hypertension)
2019 to Ongoing	Historical Condition	Kidney disorder (Renal disorder)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Servier PANAMA
COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
S25013097

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

24c. DATE RECEIVED BY MANUFACTURER
04-SEP-2025

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

DATE OF THIS REPORT
08-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25013097

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

DAFLON 1000mg Comprimidos Recubierto con Pelicula (1 DF Daily, orally) since an unknown date in 2019 to unknown date in Mar-2024 and Diabetes mellitus since an unknown date, treated with Insulin glargine (30U daily) since an unknown date.

Other medical history included Hypertension since 1980, Renal disorder since 2019.

No other concomitant medications were reported, if any.

On an unknown date, the patient experienced weight loss.

On an unknown date in Mar-2024, the patient experienced Cerebrovascular accident and Death.

The cause of death was reported as unknown.

No information was available whether an autopsy was performed on the patient or not.

Action taken regarding DAFLON 1000mg Comprimidos Recubierto con Pelicula: Not applicable

Outcome: Fatal for Death
Unknown for Weight loss and Cerebrovascular accident

Reporter assessment: No seriousness assessment provided. Not related.

The case was considered as serious (Death).

The event Cerebrovascular accident was upgraded by pharmaceutical company.

Case Comment: The case reports death of a patient while taking DAFLON (PURIFIED FLAVONOID FRACTION 1000 mg). The events Cerebrovascular accident and Weight decreased are unlisted as per RSI of DAFLON. In this case, no further information about the clinical circumstances leading to death is provided. The limited available information precludes an accurate case assessment. Hence, the causality has been assessed as unlikely.

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
#1) DAFLON 1000mg Comprimidos Recubierto con Pelicula (PURIFIED FLAVONOID FRACTION 1000 mg) Film-coated tablet, 1000 mg; Regimen #1	1000 mg, qd; Oral use	Blood purification (Blood disorder)	2019 / MAR-2024; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Diabetes mellitus (Diabetes mellitus);
Unknown to Ongoing	Historical Condition	Blood disorder NOS (Blood disorder);