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		71 Years	Female	60.00 kg			2024

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

Medication made her feel very bad [Feels bad]
Drug prescribed in an unapproved dosage regimen [Drug use for unapproved dosing regimen]

Case Description: This solicited case was received from patient in GUATEMALA and concerned a patient participating in the post authorisation study with protocol number IC4-06590-001-GTM.

The patient was a 71-year-old female (Patient ID: 2212144020101) (weight 60 kg, height 165 cm) with a medical history of hypertension and

(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) PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg)
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 1 DF, qd

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

17. INDICATION(S) FOR USE
#1) Hypertension (Hypertension)
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 2023 / 2024

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)
#1) Rivotril (Clonazepam) ; 2021 / Ongoing
#2) Vitamin C (Vitamin C) ; 2015 / Ongoing
#3) Vitamin d (Vitamin d) ; 2015 / Ongoing
#4) Vitamin e (Vitamin e) ; 2015 / Ongoing

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	Historical Condition	Hypertension (Hypertension)
Unknown to Ongoing	Historical Condition	Vascular calcification (Vascular calcification)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
SERVIER CENTRO AMERICA Y CARIBE
PANAMA

26. REMARKS
Patient ID: 2212144020101
Study ID: IC4-06590-001-GTM*

24b. MFR CONTROL NO.
S25006236

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

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

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

DATE OF THIS REPORT
09-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

calcification in the veins both since unknown date treated with PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (1 DF daily, orally) from an unknown date in 2023 to an unknown date in 2024 and then reduced to (0.5 DF daily, orally) since 2024, sleep disorder since unknown date treated with Clonazepam (1/4 DF daily, orally) since an unknown date in 2021.

Other concomitant drugs included and Vitamins C-D-E (1 DF daily each) since an unknown date in 2015 for unknown indications.

No other concomitant treatments were reported, if any.

Since unknown date, patient indicated that PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (1 tablet) made her feel very bad (did not specify) for that reason her doctor changed the dose to half a tablet daily. The intensity of the event was not obtained, it was not known whether she recovered or not.
Since an unknown date in 2024, she experienced drug prescribed in an unapproved dosage regimen, she took half tablet daily of PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 by medical prescription.

Action taken regarding PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31: Dose reduced.

Outcome of Medication made her feel very bad: Unknown
Outcome of drug prescribed in an unapproved dosage regimen: Recovered.

Reporter assessment for the event Medication made her feel very bad: Related, not serious.
Drug prescribed in unapproved dosage regimen is a special situation.
Consent to contact the doctor was not obtained.
FU requested to the patient.

Case Comment: Feeling abnormal is listed as per RSI of PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31. Considering the known side effect, medical history of sleep disorder, role of concomitant medication with missing information (therapy and event dates, outcome, investigations) the causal role is possible. Of note, PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 was given in unapproved dosing regimen.

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) PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg) Film-coated tablet, 5-1.25 mg; Regimen #1	1 DF, qd; Oral use	Hypertension (Hypertension) Calcification in the veins (Vascular calcification)	2023 / 2024; Unknown
#1) PERINDOPRIL ARG 5MG/INDAPAMIDE 1.25-F31 (PERINDOPRIL ARGININE 5 mg, INDAPAMIDE 1.25 mg) Film-coated tablet, 5-1.25 mg; Regimen #2	0.5 DF, qd; Oral use	Hypertension (Hypertension) Calcification in the veins (Vascular calcification)	2024 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Sleep disorder (Sleep disorder);