

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY PANAMA	2. DATE OF BIRTH			2a. AGE 73 Years	3. SEX Female	3a. WEIGHT 49.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
		Day	Month	Year			Day	Month	Year		
										2023	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
 Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
Allergy [Allergy]
Itching all over the body [Itching all over]
Clears throat [Throat clearing]
Hacking cough [Dry cough]
Hacking cough that choked her due to one of the components of TRIVERAM (the one that regulated the pressure, amlodipine) [Choking]
Diagnostic of cholesterol problems [Blood cholesterol abnormal]
Diagnostic of Hypertension [Hypertension]
Diagnostic of problems in the veins and blood vessels [Vein disorder NOS]
 (Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10 (ATORVASTATIN CALCIUM TRIHYDRATE 20 mg, #2) VASTAREL MR (TRIMETAZIDINE DIHYDROCHLORIDE 35 mg) (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 20 mg, qd #2) 1 DF, 3x A WEEK	16. ROUTE(S) OF ADMINISTRATION #1) Oral use #2) Oral use	
17. INDICATION(S) FOR USE #1) Cholesterol problems (Blood cholesterol) #2) Oxygenate the blood (Oxygen therapy) (Continued on Additional Information Page)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 2023 / MAY-2025 #2) 2021 / Ongoing	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 to Ongoing Historical Condition Blood cholesterol abnormal (Blood cholesterol abnormal) Unknown to Ongoing Historical Condition Hypertension (Hypertension)		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER SERVIER CENTRO AMERICA Y CARIBE PANAMA		26. REMARKS Patient ID: 41002206 Study ID: IC4-05153-001-PAN*
	24b. MFR CONTROL NO. S25010824	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 21-JUL-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 01-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Diagnostic of problems in the veins and blood vessels [Vascular disorder NOS]

Patient took 1 tablet 3 times a week (friday, saturday and sunday) of VASTAREL and stopped taking it depending on how she felt. All of this was her own decision, not a medical one [Intentional drug misuse]

Patient stopped taking TRIVERAM 20/10/10MG by her own decision [Therapy interrupted]

Case Description: This case was received from a Consumer and concerned a patient participating in the Patient support program related to protocol number (IC4-05153-001-PAN) in PANAMA.

The patient was a 73-year-old female (ID: 41002206) (Height: 148 cm and Weight: 49 kg) with medical history of cholesterol problems, hypertension, dilation of blood vessels all since unknown date was treated with ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10 (20 mg daily orally) since an unknown date in 2023 to unknown date in MAY-2025.

Other suspected drug included: VASTAREL MR (1 DF 3 times a week, orally) for oxygenate the blood since an unknown date in 2021.

No other concomitant treatment was reported if any.

In 2023 (3 months after starting with ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10 , she did not know the exact dates), she experienced Allergy, itching all over the body, clears throat, Hacking cough that choked her due to one of the components of ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10 (the one that regulated the pressure, amlodipine).

In Jul-2023, She was diagnosed with Diagnostic of cholesterol problems, Diagnostic of Hypertension and Diagnostic of problems in the veins and blood vessels.

No information was obtained on whether the diagnoses occurred while taking ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10 .

No information was obtained on whether it was related to VASTAREL use.

In unknown date, she experienced misuse. She took 1 tablet 3 times a week (friday, saturday and sunday) of VASTAREL.

She stopped taking it depending on how she felt. All of this was her own decision, not a medical one. In May-2025, patient stopped taking ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10 by her own decision.

Treatment of the reaction (Allergy): In unknown date, she took an anti-allergy medication (she didn't know the name and dose).

Action taken regarding ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10: Drug withdrawn.

Action taken regarding VASTAREL: Dose not changed.

Outcome: Not recovered for cholesterol problems, Hypertension and Diagnostic of Hypertension and Diagnostic of problems in the veins and blood vessels, Recovered for allergy, itching all over the body, clears throat, hacking cough and misuse, therapy interrupted and unknown for choking.

The seriousness assessment as per reporter was non-serious.

The causality assessment as per reporter was related for allergy, itching all over the body, clears throat, hacking cough and misuse. Unknown for diagnostic of Hypertension, diagnostic of cholesterol problems and Diagnostic of problems in the veins and blood vessels, not reported for choking.

Consent to contact the doctor was not obtained.

Case Comment: ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10

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) ATORV CAL 20-PERINDOPRIL ARG 10-AMLO 10 (ATORVASTATIN CALCIUM TRIHYDRATE 20 mg, PERINDOPRIL ARGinine 10 mg, AMLODIPINE BESILATE	20 mg, qd; Oral use	Cholesterol problems (Blood cholesterol) Hypertension (Hypertension) Dilation of blood vessels	2023 / MAY-2025; Unknown

ADDITIONAL INFORMATION**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
10 mg) Film-coated tablet; Regimen #1		(Vasodilatation)	
#2) VASTAREL MR (TRIMETAZIDINE DIHYDROCHLORIDE 35 mg) Modified-release tablet, 35 mg; Regimen #1	1 DF, 3x A WEEK; Oral use	Oxygenate the blood (Oxygen therapy)	2021 / Ongoing; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Historical Condition	Vasodilatation (Vasodilatation);
Unknown to Ongoing	Historical Condition	Oxygen therapy (Oxygen therapy);