SUSPECT ADVERSE REACTION REPORT

2025A-1401744

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
Masked	COSTA RICA	UNK	UNK	UNK	50	Female	UNK	UNK	UNK

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

1) Elevation of the liver enzyme GGT at 380 U/L (Elevated liver enzyme levels (10014480), Hepatic enzyme increased (10060795))
Unknown
2) Mild hepatic steatosis (Hepatic steatosis (10019708), Hepatic steatosis (10019708))
Unknown
3) lost a lot of weight (Lost weight (10024886), Weight decreased (10047895))
Unknown

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

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

1) CRESADEX_(ROSUVASTATINA_20_MG)_30_COMPRIMIDOS (00V025) (RSVN>ROSUVASTATIN, ROSUVASTATIN) (Suspect) (ND)

Continued

15. DAILY DOSE(S)

1) (20 milligram(s), in 1 Day)

16. ROUTE(S) OF ADMINISTRATION

1) Oral

17. INDICATION(S) FOR USE

1) Hypercholesterolemia [10020604 - Hypercholesterolemia]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (20-Mar-2025 - 20-Jul-2025)	1) 4 Months

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

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

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

1) HYPERTENSION (10020772, Hypertension) (Continuing: Yes)
Disease Comments:hypertensive crisis

Continued

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : ABBOTT GPV
Thomas Nisslein,
Freundallee 9A, Hannover, 30173, GERMANY
pv.qppv@abbott.comand49-3514-5116750

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025A-1401744
24c. DATE RECEIVED BY MANUFACTURER	**24d. REPORT SOURCE**
14-Aug-2025	☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT	**25a. REPORT TYPE**
19-Aug-2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

On 14-Aug-2025 a spontaneous valid report was received from a Physician in COSTA RICA concerning a 50 Year(s) old Female patient, who experienced Elevation of the liver enzyme GGT at 380 U/L, Mild hepatic steatosis and lost a lot of weight, under treatment with CRESADEX_(ROSUVASTATINA_20_MG)_30_COMPRIMIDOS (00V025).

The patient initiated treatment on CRESADEX_(ROSUVASTATINA_20_MG)_30_COMPRIMIDOS (00V025) on 20-Mar-2025. CRESADEX_(ROSUVASTATINA_20_MG)_30_COMPRIMIDOS (00V025) was administered as Oral, (20 milligram(s)), from 20-Mar-2025 to 20-Jul-2025. Indication for use was Hypercholesterolemia. The lot number was reported as ND.

On an unknown date the patient experienced Elevation of the liver enzyme GGT at 380 U/L. The event was considered non serious.
On an unknown date the patient experienced Mild hepatic steatosis. The event was considered non serious.
On an unknown date the patient experienced lost a lot of weight. The event was considered non serious.

The outcome of the event Elevation of the liver enzyme GGT at 380 U/L was unknown.
The outcome of the event Mild hepatic steatosis was unknown.
The outcome of the event lost a lot of weight was unknown.

CRESADEX_(ROSUVASTATINA_20_MG)_30_COMPRIMIDOS (00V025) was discontinued on 20-Jul-2025.

Concomitant medications were not reported.
Further concomitant diseases included HYPERTENSION , OBESITY and HYPERCHOLESTEROLEMIA.
There was no past medical history reported.

Causality assessment for CRESADEX_(ROSUVASTATINA_20_MG)_30_COMPRIMIDOS (00V025)
Reporter causality for the event Elevation of the liver enzyme GGT at 380 U/L: Not Reported
Reporter causality for the event Mild hepatic steatosis: Not Reported
Reporter causality for the event lost a lot of weight: Not Reported

Following information was reported:
The patient initially arrived with a hypertensive crisis and was ordered for tests. When she returned with the tests, he prescribed Cresadex 20 mg because she had elevated cholesterol and LDL, and he began
monitoring her after 4 months. When she returned after 4 months, her cholesterol and LDL levels were normal and she had lost a lot of weight, but her GGT levels were at 380 U/L. He ordered an ultrasound, and it showed mild fatty liver disease. He discontinued Cresadex for a month to see how her GGT was performing, which will be completed next week.

Pharmacovigilance Comments :

Additional Report Source:
Spontaneous

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	: CRESADEX_(ROSUVASTATINA_20_MG)_30_COMPRIMIDOS (00V025) (RSVN>ROSUVASTATIN)
Active Substance	: ROSUVASTATIN
Drug Characterization	: Suspect
Lot Number	: ND
Daily Dose	: (20 milligram(s), in 1 Day)
Route of Admin	: Oral
Indications	: Hypercholesterolemia [10020604 - Hypercholesterolemia]
Therapy Dates	: From : 20-Mar-2025 To :20-Jul-2025
Therapy Duration	: 4 Months
Action(s) Taken With Drug	: Drug withdrawn

Causality

Continuation Sheet for CIOMS report

1) Elevation of the liver enzyme GGT at 380 U/L (Elevated liver enzyme levels - 10014480, Hepatic enzyme increased - 10060795)
Causality as per reporter : Not Reported
DeChallenge : Unknown
ReChallenge : Not Applicable
2) Mild hepatic steatosis (Hepatic steatosis - 10019708, Hepatic steatosis - 10019708)
Causality as per reporter : Not Reported
DeChallenge : Unknown
ReChallenge : Not Applicable
3) lost a lot of weight (Lost weight - 10024886, Weight decreased - 10047895)
Causality as per reporter : Not Reported
DeChallenge : Unknown
ReChallenge : Not Applicable

23. OTHER RELEVANT HISTORY (Continuation...)

2) OBESITY (10029883 , Obesity)

3) HYPERCHOLESTEROLEMIA (10020604 , Hypercholesterolemia)