SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	HONDURAS		PRIVACY		74 Years	Female	83.00 kg			2019

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

Thyroidectomy [Thyroidectomy]
Low sodium [Sodium low]
Low potassium [Potassium low]
Low calcium [Calcium low]

Case Description: This solicited case was received from a Consumer in HONDURAS and concerned a patient participating in the Patient Support Program (PSP) (IC4-05762-001-HND)

The patient was an 74-year-old female (ID: 0801196507308) (Height: 150

(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) GLICLAZIDE 60MG-F30 (GLICLAZIDE) Modified-release tablet, 60 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) 120 mg, qd	#1) Oral use

17. INDICATION(S) FOR USE
#1) Diabetes (Diabetes mellitus)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 2018 / Unknown	#1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Noglucet (Sitagliptin Phosphate) ; 2018 / Ongoing
#2) Insulin NPH (Insulin isophane porcine) ; Unknown

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	Diabetes (Diabetes mellitus)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Patient ID: 0801196507308
Study ID: IC4-05762-001-HND*

24b. MFR CONTROL NO.
S25010820

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

24c. DATE RECEIVED BY MANUFACTURER
22-JUL-2025

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

DATE OF THIS REPORT
29-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: S25010820

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

cm , Weight: 83 kg) with a medical history of Diabetes since unknown date, was treated with GLICLAZIDE 60MG-F30 (120 mg daily, orally) from unknown date in 2018 to unknown date , then reduced to (60 mg daily, orally) from an unknown date, Sitagliptin Phosphate (unknown daily dose, orally) since unknown date in 2018 and Insulin isophane porcine (unknown daily dose, subcutaneous use) since unknown date.

No other concomitant treatment was reported, if any.

On 01-JUL-2025, the patient experienced low sodium, calcium and potassium. Her doctor told her it's because she did not have a thyroid, not because GLICLAZIDE 60MG-F30.

On an unknown date in 2019, the patient experienced a Thyroidectomy (assessed as Serious: Hospitalization)

The intensity of the event, if it was related to GLICLAZIDE 60MG-F30 and if she was hospitalized were not obtained.

Treatment of the reaction (Low sodium) on 17-Jul-2025 they injected her with intravenous sodium because the sodium was going down more instead of up.

Action taken regarding GLICLAZIDE 60MG-F30: Dose reduced

Outcome: Not recovered for low sodium, calcium and potassium, Unknown for Thyroidectomy.

Reporter’s causality assessment for low sodium, calcium and potassium was not related and for Thyroidectomy was not reported.

Event seriousness was no reported.

The event Thyroidectomy was considered as Serious: Hospitalization.

Case Comment: Blood sodium decreased is listed in the RSI of GLICLAZIDE 60MG-F30, while blood potassium decreased, blood calcium decreased and thyroidectomy are unlisted. Given the nature of thyroidectomy (surgical intervention) with indication not associated with GLICLAZIDE 60MG-F30, the causal role is assessed as unlikely. Based on the patient's past thyroidectomy and concomitant drugs, the reporter's opinion is maintained and the causal role is assessed as not related.

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) GLICLAZIDE 60MG-F30 (GLICLAZIDE)	60 mg, qd (dose reduced);	Diabetes (Diabetes mellitus)	Unknown;
Modified-release tablet, 60 mg; Regimen #2	Oral use		Unknown