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		51 Years	Female	Unk		DEC	2024

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

Patient administered 3 units of Basaglar instead of 15 units as prescribed by physician; (NS) blood glucose increased [Incorrect dose administered]
Glucose level had been above 250 mg/dL [Blood glucose increased]

Case Description: This solicited case, reported by a consumer via a patient support program (PSP), concerned a 51-year-old female patient of an unknown origin.

Medical history included diabetic neuropathy. Concomitant medication included gabapentin for the treatment of diabetic neuropathy.

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Insulin glargine (Insulin glargine) Pen, Disposable {Lot # D781848H; Exp.Dt. 20-APR-2026}
#2) INSULIN GLARGINE 80 (MIRIOPEN) (KWIKPEN) DEVICE (INSULIN **(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) 3 u, daily	#1) Subcutaneous
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Type 2 diabetes (Type 2 diabetes mellitus)
#2) Unknown

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) DEC-2024 / Ongoing	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) GABILEP (GABAPENTIN) Unknown ; 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	Medical Condition	Diabetic neuropathy (Diabetic neuropathy)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Eli Lilly Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
GT202504002091

24c. DATE RECEIVED BY MANUFACTURER
31-MAR-2025

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

DATE OF THIS REPORT
03-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: GT202504002091

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient received insulin glargine (rDNA origin) injections (Basaglar 100U/ml) via a pre-filled pen (Kwikpen), 3 units, daily, via subcutaneous route, for the treatment of type 2 diabetes, beginning on an unknown date in Nov-2024. On an unknown date in Nov-2024, he took 3 units of insulin glargine instead of 15 units as prescribed by the physician (incomplete dose administered) and it was not working. She did not know how and how much insulin to take correctly. Her glucose level had been above 250 mg/dL (reference range was not provided). Information regarding corrective treatment was not provided. The outcome of events was unknown. The status of insulin glargine therapy was ongoing.

The operator of the Kwikpen was patient and her training status was not provided. The general Kwikpen duration of use and suspect Kwikpen duration of use were not provided. The action taken with the suspect Kwikpen was not reported and its return was not expected.

The initial reporting consumer did not provide the relatedness assessment of the events with insulin glargine therapy and Kwikpen device.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	DEC-2024	Blood glucose Positive Above 250 (reference range was not provided).	mg/dL	

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
#2) INSULIN GLARGINE 80 (MIRIOPEN) (KWIKPEN) DEVICE (INSULIN GLARGINE 80 (MIRIOPEN) (KWIKPEN) DEVICE) Pen, Disposable {Lot # D781848H}; Regimen #1	; Unknown	Unknown	Unknown; Unknown