

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>COSTA RICA</b>	2. DATE OF BIRTH			2a. AGE <b>62 Years</b>	3. SEX <b>Female</b>	3a. WEIGHT <b>93.00 kg</b>	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
		Day	Month	Year			Day	Month	Year		
		<b>PRIVACY</b>					<b>06</b>	<b>JUL</b>	<b>2025</b>		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)  
**Flu [Influenza]  
Feels very ill [Illness]  
Patient was taking trulicity every 10 days, No AE [Inappropriate schedule of product administration]**

Case Description: Patient Demographics: 62 Years old Female

Event(s): Flu, Feels very ill, Patient was taking trulicity every 10 days, No AE

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) Trulicity 1.5mg (Dulaglutide) Solution for injection in pre-filled pen, 1.5 mg</b> (Continued on Additional Information Page)		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) other (every 10 days)</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Subcutaneous</b>	
17. INDICATION(S) FOR USE <b>#1 ) Diabetes mellitus (Diabetes mellitus)</b> (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) <b>#1 ) FEB-2024 / Unknown</b>	19. THERAPY DURATION <b>#1 ) Unknown</b>	

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) <b>#1 ) JARDIANCE DUO (EMPAGLIFLOZIN, METFORMIN HYDROCHLORIDE) Unknown ; Unknown</b>		
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	Medical Condition	Diabetes mellitus (Diabetes mellitus)
Unknown	Medical Condition	Obesity (Obesity)

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Eli Lilly Interamerica Inc (AR Branch) Tronador 4890 - Piso 12 Buenos Aires, Capital Federal CP: 1430 ARGENTINA Phone: 54 1145464000</b>		26. REMARKS
	24b. MFR CONTROL NO. <b>CR202507020924</b>	25b. NAME AND ADDRESS OF REPORTER <b>NAME AND ADDRESS WITHHELD.</b>
24c. DATE RECEIVED BY MANUFACTURER <b>19-JUL-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT <b>31-JUL-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Suspect Product(s) (Name, IFU): trulicity 1.5mg (dulaglutide) for treatment of Diabetes mellitus, Obesity

Action(s) Taken: trulicity 1.5mg (dulaglutide) - No Change

Event Outcome(s): Flu (Recovered), Feels very ill (Unknown), Patient was taking trulicity every 10 days, No AE (Unknown)

Reporter's Opinion of Relatedness: trulicity 1.5mg (dulaglutide) - Flu (Yes) , Feels very ill (Not Reported) , Patient was taking trulicity every 10 days, No AE (Yes)

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 ) Trulicity 1.5mg (Dulaglutide) Solution for injection in pre-filled pen, 1.5 mg; Regimen #1	other (every 10 days); Subcutaneous	Diabetes mellitus (Diabetes mellitus) Obesity (Obesity)	FEB-2024 / Unknown; Unknown
#1 ) Trulicity 1.5mg (Dulaglutide) Solution for injection in pre-filled pen, 1.5 mg {Lot # D750604G; Exp.Dt. 06-JUN-2026}; Regimen #2	1.5 mg, other (every 10 days); Subcutaneous	Diabetes mellitus (Diabetes mellitus) Obesity (Obesity)	Ongoing; Unknown