

## 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>49</b> Years	3. SEX <b>Female</b>	3a. WEIGHT <b>118.00</b> 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	
			<b>PRIVACY</b>						<b>MAY</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)  
**been very sleepy [Somnolence]**

Case Description: **\*\*\*This is an auto generated narrative\*\*\***

Study ID: **828652-My Healthy Journey**

Study description: Trial title: This is a 40 weeks digital patient support program with focus on exercise, motivation, nutrition & maintaining strategies (only for patients under Liraglutide 3.0 mg).

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL</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 ) 0.6 mg, qd</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Subcutaneous</b>	
17. INDICATION(S) FOR USE <b>#1 ) for weight loss (Weight control)</b>		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 ) MAY-2025 / 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)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates      Type of History / Notes      Description <b>2024 to Ongoing</b> <b>Current Condition</b> <b>Hypertension (Hypertension)</b> <b>Unknown to Ongoing</b> <b>Current Condition</b> <b>Asthmatic (Asthma)</b>		

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Novo Nordisk A/S Lise Grimmeshave Vandtaarnsvej 114 Soeborg, DK-2860 DENMARK Phone: +45 44448888</b>		26. REMARKS <b>Medically Confirmed: No</b>
	24b. MFR CONTROL NO. <b>1455414</b>	25b. NAME AND ADDRESS OF REPORTER <b>NAME AND ADDRESS WITHHELD.</b>
24c. DATE RECEIVED BY MANUFACTURER <b>09-JUN-2025</b>	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 <b>26-JUN-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

26-Jun-2025 07:09

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

Patient's height: 168 cm.

Patient's weight: 118 kg.

Patient's BMI: 41.808390.

This non-serious Solicited Report from COSTA RICA was reported by a Consumer as "been very sleepy(Sleepy)" beginning on MAY-2025 and concerned a 49 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from MAY-2025 and ongoing for "for weight loss",

Dosage Regimens:

Saxenda: ??-MAY-2025 to Not Reported, Not Reported to Not Reported (Dosage Regimen Ongoing);

Current Condition: Hypertension, Asthmatic.

Batch Numbers:

Saxenda: UNK, UNK;

Action taken to Saxenda was reported as No Change.

The outcome for the event "been very sleepy(Sleepy)" was Not recovered.

Reporter's causality (Saxenda) -

been very sleepy(Sleepy) : Possible

Company's causality (Saxenda) -

been very sleepy(Sleepy) : Unlikely

**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 ) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #2	1.2 mg, qd (applied for more than 3 weeks); Subcutaneous	for weight loss (Weight control)	Ongoing; Unknown