

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year	Unk	Male	Unk	Day	Month	Year	
		PRIVACY							Unk		
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)											
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)		Product		Serious	Listed	Reporter Causality		Company Causality			
Problemas al hablar [Logorhoea]		FORXIGA		No	No	Not Related		Not Related			
(Continued on Additional Information Page)											<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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet {Lot # Unknown}		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1) Unknown	16. ROUTE(S) OF ADMINISTRATION #1) Oral use	
17. INDICATION(S) FOR USE #1) Cardiac insufficiency (Cardiac failure)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) Ongoing	19. THERAPY DURATION #1) Unknown	

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 Unknown Unknown to Ongoing	Type of History / Notes Historical Condition Indication	Description Adverse event (Adverse event) Heart failure (Heart failure)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorgiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202506CAM020610CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00897681A
	24b. MFR CONTROL NO. 202506CAM020610CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 24-JUN-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 25-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	NAME AND ADDRESS WITHHELD.

25-Jun-2025 20:37

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

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a male patient born in 1949.

The patient's past and current medical history included adverse event (dates not reported).

No concomitant products were reported.

The patient started treatment with Forxiga (dapagliflozin) (batch number(s) Unknown) 10 milligram qd, Oral use, on an unknown date for cardiac insufficiency.

On an unknown date, the patient experienced problemas al hablar (preferred term: Logorrhoea).

The dose of Forxiga (dapagliflozin) was not changed.

At the time of reporting, the event problemas al hablar was ongoing.

The event was considered non-serious.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event (s): problemas al hablar.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): problemas al hablar.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Indication	Cardiac insufficiency (Cardiac failure);