

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE Unk	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year MAR 2025	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" 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
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	
Left leg thrombosis [Thrombosis]		DAPAGLIFLOZIN	Yes	No	Not Applicable	Related	
Left leg thrombosis [Thrombosis]		DAPAGLIFLOZIN, METFORMIN	Yes	No	Not Applicable	Related	
Very high blood sugar [Blood glucose increased]		DAPAGLIFLOZIN	No	No	Not Applicable	Related	
Very high blood sugar [Blood glucose increased]		DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Related	
(Continued on Additional Information Page)							

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet {Lot # TPO170; Exp.Dt. DEC-2026} #2) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) (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) #1) 10 milligram, qd #2) 10 milligram, single	16. ROUTE(S) OF ADMINISTRATION #1) Oral use #2) Oral use	
17. INDICATION(S) FOR USE #1) Diabetes (Diabetes mellitus) #2) Unknown (Product used for unknown indication) (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) #1) JAN-2025 / 03-MAR-2025 #2) 03-MAR-2025 / 03-MAR-2025	19. THERAPY DURATION #1) Unknown #2) 1 day	

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 to Ongoing Unknown	Type of History / Notes Current Condition Historical Condition	Description Diabetes mellitus (Diabetes mellitus) Hypertension (Hypertension)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorghe 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202508CAM000491CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00923423A
	24b. MFR CONTROL NO. 202508CAM000491CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 01-AUG-2025	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	NAME AND ADDRESS WITHHELD.
DATE OF THIS REPORT 08-AUG-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	NAME AND ADDRESS WITHHELD.

08-Aug-2025 06:46

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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Ulcer on right heel [Skin ulcer]	DAPAGLIFLOZIN	No	No	Not Applicable	Related
Ulcer on right heel [Skin ulcer]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Related
Swollen legs [Peripheral swelling]	DAPAGLIFLOZIN	No	No	Not Applicable	Related
Swollen legs [Peripheral swelling]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Related
Heart disease [Cardiac disorder]	DAPAGLIFLOZIN	No	No	Not Applicable	Not Related
Heart disease [Cardiac disorder]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Not Related

Case Description: A solicited report has been received from a physician in Patient Support Program concerning a female patient born in 1939.

The patient's past and current medical history included diabetes mellitus (ongoing), fibromyalgia (dates not reported), hypertension (dates not reported), osteoporosis (dates not reported) and spinal problems (dates not reported).

No concomitant products were reported.

During JAN-2025, the patient started treatment with Dapagliflozin (dapagliflozin) (batch number(s) TPO170) (expiration date(s) DEC-2026) 10 milligram qd, Oral use for diabetes and heart disease and with Dapagliflozin, Metformin (dapagliflozin, metformin) 10 milligram single, Oral use, on 03-MAR-2025 for unknown.

During 15-MAR-25, the patient experienced very high blood sugar (preferred term: Blood glucose increased). During 15-APR-25, the patient experienced swollen legs (preferred term: Peripheral swelling), heart disease (preferred term: Cardiac disorder) and left leg thrombosis (preferred term: Thrombosis). On an unknown date, the patient experienced ulcer on right heel (preferred term: Skin ulcer).

The dose of Dapagliflozin (dapagliflozin) was not changed. Treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) was discontinued on 03-MAR-2025.

The patient recovered from the event(s) ulcer on right heel on an unspecified date. At the time of reporting, the event left leg thrombosis was improving. The outcome of the event(s) of heart disease, swollen legs and very high blood sugar was unknown.

The reporter assessed the event of left leg thrombosis as serious due to seriousness criteria of hospitalized.

The events heart disease, swollen legs, ulcer on right heel and very high blood sugar were considered non-serious.

The reporter did not assess causality for heart disease, left leg thrombosis, swollen legs, ulcer on right heel and very high blood sugar.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): heart disease.

The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): heart disease.

The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): left leg thrombosis, swollen legs, ulcer on right heel and very high blood sugar.

The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): left leg thrombosis, swollen legs, ulcer on right heel and very high blood sugar.

Laboratory value for glycaemia was high.

Company Clinical Comment: Thrombosis is not listed in the company core data sheet of Dapagliflozin and dapagliflozin, metformin. Underlying hypertension and advance age could be confounding factor. Due to limited information on circumstances leading to event, clinical course, treatment provided, concomitant conditions, concomitant medications, detailed etiological and diagnostic work up, the evaluation did not find evidence to exclude a causal relationship between event and suspect drug.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	MAR-2025	Blood glucose	High	

ADDITIONAL INFORMATION**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) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet {Lot # TPO170; Exp.Dt. DEC-2026}; Regimen #1	10 milligram, qd; Oral use	Diabetes (Diabetes mellitus) Heart disease (Cardiac disorder)	JAN-2025 / 03- MAR-2025; Unknown
#1) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet {Lot # TPO170; Exp.Dt. DEC-2026}; Regimen #2	10 milligram, qd; Oral use	Diabetes (Diabetes mellitus) Heart disease (Cardiac disorder)	Ongoing; Unknown
#2) DAPAGLIFLOZIN, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet; Regimen #1	10 milligram, single; Oral use	Unknown (Product used for unknown indication)	03-MAR-2025 / 03- MAR-2025; 1 day

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Fibromyalgia (Fibromyalgia);
Unknown	Historical Condition	Spinal disorder (Spinal disorder); spinal problems
Unknown	Historical Condition	Osteoporosis (Osteoporosis); Prior to taking the drugs Forxiga and Xigduo
Unknown to Ongoing	Indication	Heart disease, unspecified (Cardiac disorder);
Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus);
Unknown to Ongoing	Indication	Drug use for unknown indication (Product used for unknown indication);