

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 <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	Unk	Female	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
Patient indicates that she urinates sugar [Glucose urine]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Not Related
Patient comments that she has itching on her body [Pruritus]	DAPAGLIFLOZIN, METFORMIN	No	Yes	Related	Related
Patient is waking up with sugar at 120/130 [Blood glucose increased]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Not Related
Buring in the intimate area [Vulvovaginal burning sensation]	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, METFORMIN (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # WK0047; Exp.Dt. JUL-2026}		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) 5 milligram, bid	16. ROUTE(S) OF ADMINISTRATION #1) Oral use	
17. INDICATION(S) FOR USE #1) Diabetes mellitus (Diabetes mellitus)		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) Unknown	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.) <table border="1"> <thead> <tr> <th>From/To Dates</th> <th>Type of History / Notes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>Unknown to Ongoing</td> <td>Indication</td> <td>Diabetes (Diabetes mellitus)</td> </tr> <tr> <td>Unknown to Ongoing</td> <td>Indication</td> <td>Diabetes mellitus (Diabetes mellitus)</td> </tr> </tbody> </table>			From/To Dates	Type of History / Notes	Description	Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus)	Unknown to Ongoing	Indication	Diabetes mellitus (Diabetes mellitus)
From/To Dates	Type of History / Notes	Description									
Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus)									
Unknown to Ongoing	Indication	Diabetes mellitus (Diabetes mellitus)									

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER AstraZeneca Serban Ghiorguiu 1 Medimmune Way Gaithersburg, Maryland 20878 UNITED STATES Phone: +1 301-398-0000		26. REMARKS World Wide #: CR-ASTRAZENECA-202503CAM017303CR Study ID: PSP-23269 Case References: CR-AstraZeneca-CH-00832095AM
	24b. MFR CONTROL NO. 202503CAM017303CR	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD. NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 11-JUL-2025	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 22-JUL-2025	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 2	

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
stinging in the intimate area [Vulvovaginal pain]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Related
Little things in the urine like little stars and little round things [Urine analysis abnormal]	DAPAGLIFLOZIN, METFORMIN	No	No	Not Applicable	Related
los orines eran tremendos [Urine odour abnormal]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Related
Allergy [Hypersensitivity]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Related
Molestias [Discomfort]	DAPAGLIFLOZIN, METFORMIN	No	No	Related	Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female patient born in 1947.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin, Metformin (dapagliflozin, metformin) (batch number(s) WK0047) (expiration date(s) JUL-2026) 5 milligram bid, Oral use, on an unknown date for diabetes mellitus.

On an unknown date, the patient experienced los orines eran tremendos (preferred term: Urine odour abnormal), stinging in the intimate area (preferred term: Vulvovaginal pain), patient comments that she has itching on her body (preferred term: Pruritus), patient indicates that she urinates sugar (preferred term: Glucose urine), little things in the urine like little stars and little round things (preferred term: Urine analysis abnormal), buring in the intimate area (preferred term: Vulvovaginal burning sensation), patient is waking up with sugar at 120/130 (preferred term: Blood glucose increased), molestias (preferred term: Discomfort) and allergy (preferred term: Hypersensitivity).

The report described off-label use for Dapagliflozin, Metformin.

The patient recovered from the event(s) allergy, los orines eran tremendos and molestias on an unspecified date. The outcome of the event(s) of buring in the intimate area, little things in the urine like little stars and little round things, patient is waking up with sugar at 120/130 and stinging in the intimate area was unknown. At the time of reporting, the event patient comments that she has itching on her body and patient indicates that she urinates sugar was ongoing.

The events were considered non-serious.

The reporter did not assess causality for buring in the intimate area, little things in the urine like little stars and little round things and stinging in the intimate area. The reporter considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): allergy, los orines eran tremendos, molestias, patient comments that she has itching on her body, patient indicates that she urinates sugar and patient is waking up with sugar at 120/130. The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin, Metformin and the following event(s): allergy, buring in the intimate area, little things in the urine like little stars and little round things, los orines eran tremendos, molestias, patient comments that she has itching on her body, patient indicates that she urinates sugar, patient is waking up with sugar at 120/130 and stinging in the intimate area.

Laboratory values are available.

Summary of follow-up information received by AstraZeneca on 28-Mar-2025 from consumer via Patient Support Program: New adverse events patient is waking up with sugar at 120/130, urine smell bad , little things in the urine like little stars and little round things and buring & stinging in the intimate area were added. Lab data added. narrative updated.

Summary of follow-up information received by AstraZeneca on 11-Jul-2025 from Consumer via Patient Support Program: New events "Hypersensitivity" and "Discomfort" added. Action taken updated. Outcome for event Urine odour abnormal updated. Narrative updated.

Corrected Report 17-Jul-2025: Event "Patient is waking up with sugar at 120/130" coding updated. Event "Buring & stinging in the intimate area as Buring" splitted.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose increased 10/130		