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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 & things 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
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.o. Lab Bata	•			
#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood glucose increased 10/130		