SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		Unk	Male	Unk		JAN	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
DEVELOPED SKIN ALLERGIES, SUCH AS RASHES [Dermatitis allergic]	DAPAGLIFLOZIN	No	No	Related	Related
LUNG INFECTION [Pneumonia]	DAPAGLIFLOZIN	Yes	No	Not Related	Not Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) DAPAGLIFLOZIN (DAPAGLIFLOZIN) Film-coated tablet

15. DAILY DOSE(S)
#1) Xigduo 10mg/1000mg, 1 tablet daily

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) Diabetes (Diabetes mellitus)

18. THERAPY DATES(from/to)
#1) Unknown

19. THERAPY DURATION
#1) Unknown

20. DID REACTION ABATE AFTER STOPPING DRUG?
☒ YES ☐ NO ☐ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

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
Unknown	Indication	Diabetes (Diabetes)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: GT-ASTRAZENECA-202505CAM003441GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00864205A

24b. MFR CONTROL NO.
202505CAM003441GT

24c. DATE RECEIVED BY MANUFACTURER
06-MAY-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
12-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

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 adult patient born in 1966.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Dapagliflozin (dapagliflozin) Xigduo 10mg/1000mg, 1 tablet daily, Oral use, on an unknown date for diabetes.

During 15-JAN-25, the patient experienced lung infection (preferred term: Pneumonia). On an unknown date, the patient experienced developed skin allergies, such as rashes (preferred term: Dermatitis allergic).

The patient recovered from the event(s) lung infection on an unspecified date. At the time of reporting, the event developed skin allergies, such as rashes was ongoing.

The following event(s) were considered serious due to medically significant:lung infection .

The following event was considered non-serious:developed skin allergies, such as rashes.

The reporter considered that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event (s): developed skin allergies, such as rashes. The reporter did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): lung infection .
The company physician did not consider that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): lung infection . The company physician considered that there was a reasonable possibility of a causal relationship between Dapagliflozin and the following event(s): developed skin allergies, such as rashes.