SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Female	Unk		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 was unwell [Malaise]	XIGDUO	No	No	Not Applicable	Not Related
Patient was unwell [Malaise]	KOMBIGLYZE XR	No	No	Not Applicable	Related
Vision is blurry [Vision blurred]	XIGDUO	No	No	Not Applicable	Not Related
Vision is blurry [Vision blurred]	KOMBIGLYZE XR	No	No	Not Applicable	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) XIGDUO (DAPAGLIFLOZIN, METFORMIN) Tablet {Lot # WF0210; Exp.Dt. APR-2026}
#2) KOMBIGLYZE XR (SAXAGLIPTIN, METFORMIN) Tablet

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

15. DAILY DOSE(S)
#1) 10 milligram, qd
#2) 5 milligram, qd

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

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

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

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

19. THERAPY DURATION
#1) Unknown
#2) 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	Type of History / Notes	Description
Unknown	Historical Condition	Eye operation (Eye operation)
	6 or 7 years ago (exact date not provided)	
Unknown to Ongoing	Indication	Diabetes (Diabetes mellitus)

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 #: CR-ASTRAZENECA-202504CAM027016CR
Study ID: PSP-23269
Case References: CR-AstraZeneca-CH-00860241A

24b. MFR CONTROL NO.
202504CAM027016CR

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
30-APR-2025

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

DATE OF THIS REPORT
07-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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
Head problem [Head discomfort]	XIGDUO	No	No	Not Applicable	Related
Head problem [Head discomfort]	KOMBIGLYZE XR	No	No	Not Applicable	Related
Ear problem [Ear disorder]	XIGDUO	No	No	Not Applicable	Related
Ear problem [Ear disorder]	KOMBIGLYZE XR	No	No	Not Applicable	Related

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

The patient’s past and current medical history included eye surgery (dates not reported).

No concomitant products were reported.

The patient started treatment with Kombiglyze Xr (saxagliptin, metformin) 5 milligram qd, Oral use, on an unknown date and with Xigduo (dapagliflozin, metformin) (batch number(s) WF0210) (expiration date(s) APR-2026) 10 milligram qd, Oral use, on an unknown date for diabetes.

On an unknown date, the patient experienced vision is blurry (preferred term: Vision blurred), patient was unwell (preferred term: Malaise), ear problem (preferred term: Ear disorder) and head problem (preferred term: Head discomfort).

The patient recovered from the event(s) ear problem, head problem, patient was unwell and vision is blurry on an unspecified date.

The events were considered non-serious.

The reporter did not assess causality for ear problem, head problem, patient was unwell and vision is blurry.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Kombiglyze Xr and the following event(s): vision is blurry. The company physician did not consider that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): patient was unwell and vision is blurry. The company physician considered that there was a reasonable possibility of a causal relationship between Kombiglyze Xr and the following event(s): ear problem, head problem and patient was unwell. The company physician considered that there was a reasonable possibility of a causal relationship between Xigduo and the following event(s): ear problem and head problem.