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	Male	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
Palpitations [Palpitations]	BREZTRI	No	Yes	Related	
Palpitations [Palpitations]	EvocapXS Metered Dose Inhaler	No	No	Related	
general destabilization [General physical condition abnormal]	BREZTRI	No	No	Related	
general destabilization [General physical condition abnormal]	EvocapXS Metered Dose Inhaler	No	No	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) BREZTRI (BUDESONIDE, GLYCOPYRRONIUM, FORMOTEROL) Pressurised inhalation {Lot # Unknown}
#2) EvocapXS Metered Dose Inhaler (EvocapXS Metered Dose Inhaler) Unknown

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

15. DAILY DOSE(S)
#1) UNK
#2)

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown
#2) Unknown

17. INDICATION(S) FOR USE
#1) COPD (Chronic obstructive pulmonary disease)
#2) COPD (Chronic obstructive pulmonary disease)

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 to Ongoing	Indication	COPD (COPD)
Unknown	Procedure with stents	Cardiac operation (Cardiac operation)

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-202505CAM006686CR
Case References: CR-AstraZeneca-CH-00866836A

24b. MFR CONTROL NO.
202505CAM006686CR

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
12-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202505CAM006686CR

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a consumer. The report concerns a male patient (age not provided) of Hispanic ethnic origin.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Breztri (budesonide, glycopyrronium, formoterol) (batch number(s) Unknown) UNK, on an unknown date for copd.

It is unknown who administered Breztri to the patient.

On an unknown date, the patient experienced general destabilization (preferred term: General physical condition abnormal) and palpitations (preferred term: Palpitations).

The patient recovered from the event(s) general destabilization and palpitations on an unspecified date.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Breztri and the following event(s): general destabilization and palpitations. The reporter considered that there was a reasonable possibility of a causal relationship between Evocapxs Metered Dose Inhaler and the following event(s): general destabilization and palpitations.

Device Information:
Combination Product Report: Yes
Product As Reported: Breztri
Brand Name: BREZTRI
Product Role:Suspect
Manufacturer Name:ASTRAZENECA
Labeled for single use:No