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	GUATEMALA		PRIVACY		76 Years	Female	Unk	11	FEB	2025

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
Bronchopneumonia [Pneumonia]	BUDESONIDE, FORMOTEROL	Yes	Yes	Not Applicable	Not Related
Bronchopneumonia [Pneumonia]	Turbuhaler Dry Powder Inhaler	Yes	No	Not Applicable	Not Related
Symbicort Turbohaler for COPD [Off label use]	BUDESONIDE, FORMOTEROL	No	No	Not Applicable	Not Applicable
Symbicort Turbohaler for COPD [Off label use]	Turbuhaler Dry Powder Inhaler	No	No	Not Applicable	Not Applicable

(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) BUDESONIDE, FORMOTEROL (BUDESONIDE, FORMOTEROL) Inhalation powder {Lot # XMBA; Exp.Dt.
#2) Turbuhaler Dry Powder Inhaler (Turbuhaler Dry Powder Inhaler) **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)
#1) 160/4.5 mic (Continued on Additional Information Page)
#2)

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

17. INDICATION(S) FOR USE
#1) Asthma (Asthma)
#2) Unknown **(Continued on Additional Information Page)**

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

18. THERAPY DATES(from/to)
#1) 2021 / 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	Indication	Asthma (Asthma)
Unknown	Indication	COPD (Chronic obstructive pulmonary disease)

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-202505CAM008552GT
Study ID: PSP-23269
Case References: GT-AstraZeneca-CH-00868241AP

24b. MFR CONTROL NO.
202505CAM008552GT

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
15-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202505CAM008552GT

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A solicited report has been received from a consumer in Patient Support Program concerning a female elderly patient born in 1948 (age 76 years).

No medical history was reported. No concomitant products were reported.

The patient started treatment with Budesonide, Formoterol (budesonide, formoterol) (batch number XMBA) (expiration date(s) DEC-2025) 160/4.5 microgram per Inhalation, every 8 hours, Inhalation use, during 2021 for asthma and copd.

On 11-FEB-25, the patient experienced bronchopneumonia (preferred term: Pneumonia). On an unknown date, the patient experienced symbicort turbohaler for copd (preferred term: Off label use).

The report described off-label use for Budesonide, Formoterol. The reported term was symbicort turbohaler for copd (preferred term: Off label use).

It is unknown if any action was taken with Budesonide, Formoterol (budesonide, formoterol).

The outcome of the event(s) of symbicort turbohaler for copd was unknown. The outcome of the event(s) of bronchopneumonia was unknown.

The following event(s) were considered serious due to hospitalized:bronchopneumonia.

The following event was considered non-serious:symbicort turbohaler for copd.

The reporter did not assess causality for bronchopneumonia and symbicort turbohaler for copd.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Budesonide, Formoterol and the following event: bronchopneumonia.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Turbuhaler Dry Powder Inhaler and the following event: bronchopneumonia.

Device Information:
Combination Product Report: Yes
Product As Reported: Budesonide, Formoterol
Brand Name: BUDESONIDE, FORMOTEROL
Product Role:Suspect
Manufacturer Name:ASTRAZENECA
Labeled for single use:No

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) BUDESONIDE, FORMOTEROL (BUDESONIDE, FORMOTEROL) Inhalation powder {Lot # XMBA; Exp.Dt. DEC-2025}; Regimen #1	160/4.5 microgram per Inhalation, q8h; Inhalation use	Asthma (Asthma) COPD (Chronic obstructive pulmonary disease)	2021 / Unknown; Unknown
#2) Turbuhaler Dry Powder Inhaler (Turbuhaler Dry Powder Inhaler) Unknown; Regimen #1	; Unknown	Unknown	Unknown; Unknown