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	13	MAY	2024

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
PAIN WHEN PLACING THE MEDICATION [Injection site pain]	FASENRA PEN	No	Yes	Related	Related
PAIN WHEN PLACING THE MEDICATION [Injection site pain]	YpsoMate Automatic Injector	No	No	Related	Not Related
Fever [Pyrexia]	FASENRA PEN	No	Yes	Related	Related
Fever [Pyrexia]	YpsoMate Automatic Injector	No	No	Related	Not Related
Cansancio [Fatigue]	FASENRA PEN	No	No	Related	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) FASENRA PEN (BENRALIZUMAB) Solution for injection in pre-filled pen
#2) YpsoMate Automatic Injector (YpsoMate Automatic Injector) Unknown

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

15. DAILY DOSE(S)
#1) 30 milligram, q8w
#2)

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

17. INDICATION(S) FOR USE
#1) severe eosinophilic asthma (Asthma)
#2) severe eosinophilic asthma (Asthma)

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

18. THERAPY DATES(from/to)
#1) 11-DEC-2023 / Ongoing
#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	Eosinophilic asthma (Asthma)

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-2024A124026
Study ID: PSP-23269
Case References: CR-AstraZeneca-2024-208630
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24b. MFR CONTROL NO.
2024A124026

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
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: 1

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
Cansancio [Fatigue]	YpsoMate Automatic Injector	No	No	Related	Not Related

Case Description: A solicited report has been received from a consumer in Patient Support Program. The report concerns a female adult patient born in 1977.

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Fasenra Pen (benralizumab) 30 milligram, Subcutaneous use, on 11-DEC-2023 for severe eosinophilic asthma.

It is unknown who administered Fasenra Pen to the patient.

On 13-MAY-24, the patient experienced pain when placing the medication (preferred term: Injection site pain). On an unknown date, the patient experienced fever (preferred term: Pyrexia) and cansancio (preferred term: Fatigue).

The dose of Fasenra Pen (benralizumab) was not changed.

The patient recovered from the event(s) cansancio and fever on an unspecified date. The patient recovered from the event(s) pain when placing the medication after 2 days on 14-MAY-2024.

The events were considered non-serious.

The reporter considered that there was a reasonable possibility of a causal relationship between Fasenra Pen and the following event (s): cansancio, fever and pain when placing the medication. The reporter considered that there was a reasonable possibility of a causal relationship between Ypsomate Automatic Injector and the following event(s): cansancio, fever and pain when placing the medication.
The company physician did not consider that there was a reasonable possibility of a causal relationship between Ypsomate Automatic Injector and the following event(s): cansancio, fever and pain when placing the medication. The company physician considered that there was a reasonable possibility of a causal relationship between Fasenra Pen and the following event(s): cansancio, fever and pain when placing the medication.

Device Information:
Combination Product Report: Yes
Product As Reported: Fasenra Pen
Brand Name: FASENRA PEN
Product Role:Suspect
Additional manufacturer narrative:Insufficient information was received in the report to determine which device was used to administer Fasenra. The device YpsoMate Automatic Injector has been selected for the purposes of enabling combination product reporting in applicable territories.
Manufacturer Name:ASTRAZENECA
Labeled for single use:No

Summary of follow-up information received by AstraZeneca 30-APR-2025 from consumer via spontaneous report: New non serious events of Fatigue and Fever were added. Narrative updated.