CIOMS FORM

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	COSTA RICA		PRIVACY		36 Years	Female	Unk	27	MAR	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
HEADACHE [Headache]	FASENRA PEN	No	No	Related	Related
TIREDNESS [Fatigue]	FASENRA PEN	No	No	Related	Related
rash on arms and legs [Rash]	FASENRA PEN	No	No	Related	Related
itches and burns [Pruritus]	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 asthma (Asthma)
#2) Severe asthma (Asthma)

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

18. THERAPY DATES(from/to)
#1) 27-MAR-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	Asthma (Asthma)
Unknown	Historical Condition	Atopic dermatitis (Dermatitis atopic)

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-2023A208069
Study ID: PSP-23269
Case References: CR-AstraZeneca-2023A208069
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24b. MFR CONTROL NO.
2023A208069

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

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

DATE OF THIS REPORT
05-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.
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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 female adult patient born in 1988 (age 36 years).

The patient's past and current medical history included atopic dermatitis (dates not reported).

No concomitant products were reported.

The patient started treatment with Fasenra Pen (benralizumab) 30 milligram q8w, Subcutaneous use, on 27-MAR-2023 for severe asthma.

It is unknown who administered Fasenra Pen to the patient.

On 27-MAR-25, the patient experienced rash on arms and legs (preferred term: Rash) and itches and burns (preferred term: Pruritus). On an unknown date, the patient experienced headache (preferred term: Headache) and tiredness (preferred term: Fatigue).

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

At the time of reporting, the event headache, itches and burns, rash on arms and legs and tiredness was ongoing.

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): headache, itches and burns, rash on arms and legs and tiredness. The reporter considered that there was a reasonable possibility of a causal relationship between Ypsomate Automatic Injector and the following event(s): headache, itches and burns, rash on arms and legs and tiredness.
The company physician considered that there was a reasonable possibility of a causal relationship between Fasenra Pen and the following event(s): headache, itches and burns, rash on arms and legs and tiredness. The company physician considered that there was a reasonable possibility of a causal relationship between Ypsomate Automatic Injector and the following event(s): headache, itches and burns, rash on arms and legs and tiredness.

Device Information:
Combination Product Report: Yes
Product As Reported: Fasenra Pen
Brand Name: FASENRA PEN
Product Role:Suspect
Manufacturer Name:ASTRAZENECA
Labeled for single use:No

Summary of follow up information received by AstraZeneca on 28-APR-2025 from consumer via Patient Support Program. Event: the patient experienced rash on arms and legs, itches and burns were added. Past medical history was added. Narrative updated. Corrected report on 2-May-2025: Device component was added. Report type was updated.