**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 | | 63 Years | Female | Unk | 11 | OCT | 2023 |

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 |
|---|---|---|---|---|---|
| STIFFNESS IN THE LEGS [Musculoskeletal stiffness] | FASENRA PEN | No | No | Related | Related |
| STIFFNESS IN THE LEGS [Musculoskeletal stiffness] | YpsoMate Automatic Injector | No | No | Related | Not Related |
| LEG PAIN [Pain in extremity] | FASENRA PEN | No | No | Related | Related |
| LEG PAIN [Pain in extremity] | YpsoMate Automatic Injector | No | No | Related | Not Related |
| Vómito [Vomiting] | 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 {Lot # Unknown}
#2 ) YpsoMate Automatic Injector (YpsoMate Automatic Injector) Unknown **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)
#1 ) 30 milligra (Continued on Additional Information Page)
#2 )

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

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

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

18. THERAPY DATES(from/to)
#1 ) 19-JUN-2023 / 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 | 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-2023A284606
Case References: CR-AstraZeneca-2023A284606
1

24b. MFR CONTROL NO.
**2023A284606**

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

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

DATE OF THIS REPORT
06-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

Mfr. Control Number: 2023A284606

## 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 |
|---|---|---|---|---|---|
| Vómito [Vomiting] | YpsoMate Automatic Injector | No | No | Related | Not Related |

Case Description: A solicited report from a non-interventional study/data collection program has been received from from a consumer. The report concerns a female adult patient of Unknown ethnic origin born in 1959 (age 63 years).

No medical history was reported.

No concomitant products were reported.

The patient started treatment with Fasenra Pen (benralizumab) (batch number(s) Unknown) 30 milligram q8w, Subcutaneous use, on 19-JUN-2023 for severe asthma.

It is unknown who administered Fasenra Pen to the patient.

On 11-OCT-23, the patient experienced stiffness in the legs (preferred term: Musculoskeletal stiffness) and leg pain (preferred term: Pain in extremity). On an unknown date, the patient experienced vómito (preferred term: Vomiting).

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

The patient recovered from the event(s) vómito on an unspecified date. The outcome of the event(s) of leg pain and stiffness in the legs was unknown.

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): leg pain, stiffness in the legs and vómito. The reporter considered that there was a reasonable possibility of a causal relationship between Ypsomate Automatic Injector and the following event(s): leg pain, stiffness in the legs and vómito.
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): leg pain, stiffness in the legs and vómito. The company physician considered that there was a reasonable possibility of a causal relationship between Fasenra Pen and the following event(s): leg pain, stiffness in the legs and vómito.

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 significant follow up information received by AstraZeneca/MedImmune 28-Apr-2025 from consumer via Non-Interventional Study New event vomiting was added. Causality was added. Device information was added.Narrative updated.

**14-19. SUSPECT DRUG(S) continued**

| 14. SUSPECT DRUG(S) (include generic name) | 15. DAILY DOSE(S);<br>16. ROUTE(S) OF ADMIN | 17. INDICATION(S) FOR USE | 18. THERAPY DATES (from/to);<br>19. THERAPY DURATION |
|---|---|---|---|
| #1 ) FASENRA PEN (BENRALIZUMAB) Solution for injection in pre-filled pen {Lot # Unknown}; Regimen #1 | 30 milligram, UNK, Frequency: Q8WK; Subcutaneous use | severe asthma (Asthma) | 19-JUN-2023 / Unknown; Unknown |