CIOMS FORM

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	PANAMA		PRIVACY		45 Years	Female	Unk	27	MAR	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Cold symptoms/nasal congestion/Fever/Sore throat/ Severe cold [Cold]
Back pain [Back pain]
Weakness [Weakness]
sleepy [Sleepy]
chills [Chills]
Fatigue [Fatigue]
Nausea [Nausea]
decreased appetite [Decreased appetite]
Headache [Headache]
swelling in both feet and hip [Swelling]

(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) AMGEVITA (adalimumab) Solution for injection
#2) single dose prefilled syringe (single dose prefilled syringe) Device

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 40 milligram, every 15 days	#1) Subcutaneous use
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Ankylosing spondylitis/Spondylitis (An
#2) Ankylosing spondylitis/Spondylitis (Ankylos

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 14-FEB-2025 / Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) Carbamazepine (Carbamazepine) ; Ongoing
#2) Clonazepam (Clonazepam) ; Ongoing
#3) Desmopressin (Desmopressin) ; Ongoing
#4) Loratadine (Loratadine) ; Ongoing
#5) Acetaminophen (Acetaminophen) ; Unknown

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	Current Condition	Ankylosing spondylitis (Ankylosing spondylitis)
Unknown	Procedure	Surgery (Surgery)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Amgen Ltd.
Ana Carolina Uribe
Cra 7 No. 123-35 Torre 123 Piso 6
Bogotá, COLOMBIA
Phone: 57 3157008539

26. REMARKS

24b. MFR CONTROL NO.
PANSL2025063827

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

24c. DATE RECEIVED BY MANUFACTURER
30-JUN-2025

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

DATE OF THIS REPORT
04-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Right ankle pain/Left knee pain [Pain in ankle]
Body discomfort [Malaise]
spine hurts more [Spinal pain]
Generalized body pain [General body pain]

Case Description: This non-serious solicited report (PANSL2025063827) was reported to Amgen on 28/MAR/2025 by a consumer from a commercial program (PSP10850) and involves a 45-year-old female patient who had nasal congestion/symptoms [PT: nasopharyngitis], back pain [PT: back pain] while receiving Amgevita, Single Dose Prefilled Syringe (adalimumab, manufacturer Amgen).

No historical medical condition was reported. The patient's current medical condition included spondylitis. No concomitant medications were provided. No co-suspect medications were reported.

The patient began Amgevita, Single Dose Prefilled Syringe on 21/FEB/2025. On 27/MAR/2025, the patient had a lot of nasal congestion. She was going to catch a cold/ cold symptoms and back pain. No treatment information was received. The outcome of the events nasopharyngitis, back pain were reported as not recovered/not resolved. Action taken with Amgevita, Single Dose Prefilled Syringe was continued for the events nasopharyngitis and back pain.

The causal relationship between the events nasopharyngitis, back pain and Amgevita, Single Dose Prefilled Syringe was not provided by the consumer. No follow-up attempts are possible. No further information is expected.

ADDITIONAL INFORMATION RECEIVED ON 07/APR/2025:
The patient's surgical history included head surgery, no pituitary gland. The patient's current medical condition included diabetes insipidus because she lacks a pituitary gland, and because of not having one, she had no control over the "Cinteres" (unknown) in her urine. The patient's concomitant medications included Carbamazepine (carbamazepine), Clonazepam (clonazepam), Desmopressin (desmopressin), Loratadine (loratadine), Acetaminophen (acetaminophen). The patient reported that her side effects had decreased. Since starting treatment with Amgevita (date not specified), for 3 or 4 days, she had experienced extreme weakness [PT: asthenia], sleepiness [PT: somnolence], chills [PT: chills], a feeling of fatigue [PT: fatigue], mild nausea [PT: nausea], a decreased appetite [PT: decreased appetite], and a headache [PT: headache]. However, with the last dose of Amgevita, she felt a little better and no longer as bad. She comments that symptoms were not (very severe) enough to warrant a physician's appointment. (Results of extreme weakness, increased sleepiness, nausea, decreased appetite, and headache were recovered). She mentions that she also feels better from the swelling in both feet and hip [PT: swelling]. She comments that she had felt less pain in her right ankle, which was bad, and in the knee of her left leg [PT: arthralgia], but that her entire spine hurts more [PT: spinal pain]. She also reported that for the past 4 to 5 days, without a date, she had a cold, nasal congestion, and a sore throat. She also had a fever 3 days earlier, without a date. Outcome of the sore throat adverse event was recovering. Outcome of the fever adverse event was recovered. She reported that she did not remember when she started taking Amgevita, only that she had 4 injections and that her next dose would due on Friday, 11/APR/2025. She did not have the expiration date or lot number for Amgevita because she discarded the box. No treatment information was received. The outcome of the events nasopharyngitis, arthralgia were reported as recovering/resolving. The outcome of the events asthenia, somnolence, chills, fatigue, nausea, decreased appetite, headache, swelling were reported as recovered/resolved. The outcome of the event spinal pain was reported as unknown. The events asthenia, somnolence, chills, fatigue, nausea, decreased appetite, headache, swelling were resolved on an unknown date. Action taken with Amgevita, Single Dose Prefilled Syringe was continued for the events asthenia, somnolence, chills, fatigue, nausea, decreased appetite, headache, swelling, arthralgia and spinal pain. The causal relationship between the events asthenia, somnolence, chills, fatigue, nausea, decreased appetite, headache, swelling, arthralgia, spinal pain and Amgevita, Single Dose Prefilled Syringe was not provided by the consumer. Follow up has been requested.

ADDITIONAL INFORMATION RECEIVED ON 23/APR/2025:
In this follow up lot number added for Amgevita. On 22/APR/2025, the patient started with a severe cold and had a fever. On 23/APR/2025, she continued with the severe cold, felt chills, body discomfort and felt unwell [PT: malaise]. She indicates that she would visit her general practitioner on the day of this report (Today) to receive medication for her congestion, as she was quite congested. She applied Arngevita every other Friday, that was, every two weeks, because she was an educator and applied it on Fridays so she could rest more on the weekend. Her fever recovered. Her next Amgevita application was scheduled for 25/APR/2025. The outcome of the events malaise, nasopharyngitis, chills was reported as not recovered/not resolved. Action taken with Amgevita, Single Dose Prefilled Syringe was continued for the events malaise. The other manufacturers reported that the events nasopharyngitis, back pain, asthenia, somnolence, chills, fatigue, nausea, decreased appetite, headache, swelling, arthralgia, malaise was possibly related to Amgevita. The causal relationship between the event malaise and Amgevita, Single Dose Prefilled Syringe was not provided by the consumer.

ADDITIONAL INFORMATION RECEIVED ON 30/JUN/2025:
The patient's current medical condition includes rheumatoid arthritis and has no control of urine cynteres (unknown). On 22/JUN/2025, the patient had generalized body pain [PT: pain]. The patient had received unspecified pain medication. The outcome for the event pain was recovered/resolved. The event was recovered/resolved on 24/JUN/2025. The action taken was continued for the event pain. The other manufacturers reported that the event pain not related to Amgevita. The causal relationship between the event pain and Amgevita, Single Dose Prefilled Syringe was not provided by the consumer

ADDITIONAL INFORMATION

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) AMGEVITA (adalimumab) Solution for injection; Regimen #1	40 milligram, every 15 days; Subcutaneous use	Ankylosing spondylitis/Spondylitis (Ankylosing spondylitis) rheumatoide Arthritis (Rheumatoid arthritis)	14-FEB-2025 / Unknown; Unknown
#1) AMGEVITA (adalimumab) Solution for injection {Lot # 1174976; Exp.Dt. 30-SEP-2026}; Regimen #2	40 milligram; Subcutaneous use	Ankylosing spondylitis/Spondylitis (Ankylosing spondylitis) rheumatoide Arthritis (Rheumatoid arthritis)	21-FEB-2025 / Ongoing; Unknown
#2) single dose prefilled syringe (single dose prefilled syringe) Device; Regimen #1	; Unknown	Ankylosing spondylitis/Spondylitis (Ankylosing spondylitis) rheumatoide Arthritis (Rheumatoid arthritis)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Diabetes insipidus (Diabetes insipidus);
Unknown	Procedure	Pituitary gland operation (Pituitary gland operation);
Unknown to Ongoing	Current Condition	Ill-defined disorder (Ill-defined disorder);
Unknown to Ongoing	Current Condition	Rheumatoid arthritis (Rheumatoid arthritis);