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		57 Years	Female	Unk		Unk	

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

Welts [Welts]
a dose of 40 mg every month [Off label dosing frequency]

Case Description: This non-serious solicited report (PANSL2024207645) was reported to Amgen on 17/OCT/2024 by a consumer from a commercial program (PSP10850) and involves a 57 year old female patient who had welts [PT: urticaria] while receiving Amgevita (adalimumab, manufacturer Amgen). Off label use was reported.

No historical medical condition was reported.

(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

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 40 milligram, qmo

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

17. INDICATION(S) FOR USE
#1) Psoriasis (Psoriasis)

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

18. THERAPY DATES(from/to)
#1) 01-FEB-2023 / Unknown

19. THERAPY DURATION
#1) 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	Current Condition	Psoriasis (Psoriasis)

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.
PANSL2024207645

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

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

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

DATE OF THIS REPORT
30-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

The patient began Amgevita on 01/FEB/2023. It was reported that at the beginning the patient received Amgevita 2 applications per month. But when the physician noticed the patient's improvement in welt suspended one dose so she received Amgevita monthly lately (off label use). She had suspended Amgevita treatment because approximately 2 or 3 months prior to this report (2024), as she no longer had welts and her skin was very clean as if she never had welts, patient commented that. She did not know how long the treatment would be suspended because the physician told her that would only suspend the treatment for a while, but did not tell her for how long it would be. She applied unspecified moisturizing creams to her skin and applied it to moisturize the whole body, such as the hands, legs and back, after bathing, but if she noticed she did not need it anymore, she only applied it once a day and did not use "insurance" medication. Her last dose of Amgevita was applied approximately in JUL/2024 or AUG/2024, and in those same dates the treatment of Amgevita was suspended to the patient. Because at that time she was already showing improvement, she had some welts, and suddenly it disappeared, that was to told, she no longer had welts. When physician checked, decided to suspend Amgevita, so that after a while could see if she would not get welts again. But she had not gotten welts again and that she hope that she would not get welts again. When she only applied Amgevita one per month, to give time for the treatment to fulfill its function of completely eliminating the welts in the patient. Her next appointment with the dermatologist was every 4 months, approximately in mid- DEC/2024, since the patient's skin was well cleaned, she refers that she did not need to visit the dermatologist so often. The outcome of the event urticaria was reported as resolving/recovering. Action taken with Amgevita was withdrawn for the event urticaria.

The causal relationship between the event urticaria and Amgevita was not provided by the consumer. Lot number has been requested. Follow up has been requested.

ADDITIONAL INFORMATION WAS RECEIVED ON 12/NOV/2024:
No follow-up attempts are possible. No further information is expected.

ADDITIONAL INFORMATION WAS RECEIVED ON 23/APR/2025:
It was reported that the Amgevita treatment was still being suspended because the doctor was waiting for the patient to experience a reaction. However, she had not experienced any reaction (such as hives). She was recovered because she no longer had a single hive on her body. Those hives had dissolved and no more had appeared. She did not remember the last dose of Amgevita she took. Any progress of reaction she experienced would be reported to the nurse who monitors her in the country. At the beginning of treatment, she took 40 milligram monthly, but later she took 50 milligram monthly because her rashes were getting worse every day. On 28/FEB/2023, she received 40 milligram monthly. The outcome of the event urticaria was reported as recovered/resolved. The event urticaria was resolved on an unknown date.

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 #2	50 milligram, qmo; Subcutaneous use	Psoriasis (Psoriasis)	Unknown; Unknown
#1) AMGEVITA (adalimumab) Solution for injection; Regimen #3	40 milligram, qmo; Subcutaneous use	Psoriasis (Psoriasis)	28-FEB-2023 / Unknown; Unknown