

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY GUATEMALA	2. DATE OF BIRTH Day Month Year PRIVACY	2a. AGE 76 Years	3. SEX Male	3a. WEIGHT Unk	4-6 REACTION ONSET Day Month Year Unk	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING <input type="checkbox"/> CONGENITAL ANOMALY <input type="checkbox"/> OTHER
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas) Prolia Indication: bone cancer metastatic/Dose/frequency: 120mg every 3 months [Off label use] Case Description: This non-serious spontaneous report (GT MSP2025108172) was reported to Amgen on 28/MAY/2025 by a consumer and involves a 76 years old male patient who received Prolia, Single Dose Prefilled Syringe. (Continued on Additional Information Page)							

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Prolia (denosumab) Solution for injection {Lot # L14177A1} #2) single dose prefilled syringe (single dose prefilled syringe) Device (Continued on Additional Information Page)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 60 milligra (Continued on Additional Information Page) #2)	16. ROUTE(S) OF ADMINISTRATION #1) Unknown #2) Unknown
17. INDICATION(S) FOR USE #1) spinal cancer (Bone cancer metastatic) #2) bone cancer metastatic (Bone cancer metastatic)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 20-MAY-2024 / 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) #1) Acetaminophen (Paracetamol) Unknown formulation ; Unknown #2) Bicalutamide (Bicalutamide) Tablet ; 19-MAR-2024 / Unknown #3) Tramacet (Paracetamol, Tramadol hydrochloride) Capsule ; 20-MAY-2024 / 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 Prostate cancer metastatic (Prostate cancer metastatic) Unknown to Ongoing Current Condition Prostate cancer metastatic (Prostate cancer metastatic)

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. GT MSP2025108172	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER 28-MAY-2025	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous
DATE OF THIS REPORT 05-JUN-2025	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Off label use was reported.

The patient's historical medical condition included flu-like symptoms, heart problems, pain in the lower limbs, headache, abnormal total prostate antigen. The patient's current medical condition included prostate cancer, spinal cancer, abdominal spasm, chills, intense heat, excess sweating. The patient's concomitant medications included Acetaminophen (paracetamol), Bicalutamide (bicalutamide), Tramacet (paracetamol, tramadol hydrochloride). The patient's co-suspect medication included Eligard (leuporelin acetate), Xtandi (enzalutamide). On an unknown date in JAN/2024, the patient's laboratory test(s) included Prostatic specific antigen, revealing 900 ng/mL. On 17/MAY/2024, the patient's laboratory test(s) included Prostatic specific antigen, revealing 0 ng/mL.

The patient began Prolia, Single Dose Prefilled Syringe on 20/MAY/2024, 120 mg every 3 months for spinal cancer (off label use). No treatment information was received.

No follow-up attempts are possible. No further information is expected.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	JAN-2024	Prostatic specific antigen Done	900 ng/mL	
2	17-MAY-2024	Prostatic specific antigen Done	0 ng/mL	

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) Prolia (denosumab) Solution for injection {Lot # L14177A1}; Regimen #1	60 milligram (2 pre-filled syringes of 120 mg every 3 months); Unknown	spinal cancer (Bone cancer metastatic)	20-MAY-2024 / Unknown; Unknown
#3) Eligard (Leuporelin acetate) Inhalation powder; Regimen #1	22.5 milligram, q3mo; Subcutaneous use	Prostate cancer (Prostate cancer)	09-FEB-2024 / Unknown; Unknown
#3) Eligard (Leuporelin acetate) Inhalation powder {Lot # L14177A1}; Regimen #2	45 milligram, q6mo; Subcutaneous use	Prostate cancer (Prostate cancer)	23-MAY-2024 / Ongoing; Unknown
#4) Xtandi (Enzalutamide) Capsule; Regimen #1	40 milligram (4 capsules together every 24 hours, 120 CAP x 30 END); Oral use	Spinal cancer (Bone cancer metastatic)	20-MAY-2024 / Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Historical Condition	Flu-like symptoms (Influenza like illness);
Unknown	Historical Condition	Cardiac disorder (Cardiac disorder);
10-FEB-2024 to Unknown	Historical Condition	Pain in extremity (Pain in extremity);
10-FEB-2024 to Unknown	Historical Condition	Headache (Headache);
08-MAR-2024 to Ongoing	Current Condition	Abdominal spasm (Abdominal rigidity);
JAN-2024 to Unknown	Historical Condition	Prostatic specific antigen abnormal (Prostatic specific antigen

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
		abnormal);
Unknown to Ongoing	Current Condition	Chills (Chills);
FEB-2025 to Ongoing	Current Condition	Feeling hot (Feeling hot);
FEB-2025 to Ongoing	Current Condition	Excess sweating (Hyperhidrosis);