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		32 Years	Female	Unk			2025

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

headaches had worsened [Headache aggravated]

Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974.

A 32-year-old female patient received rimegepant (NURTEC ODT), first regimen from Feb2025 to 2025 at 75 mg (75 mg, 3 times per month) and second regimen since 2025 at 75 mg alternate day for headache. The patient's relevant medical history included: "Epilepsy" (ongoing); "Migraine" (ongoing). Concomitant medication(s) included: MAXALT sublingual.

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Nurtec ODT (RIMEGEPANT) Orodispersible tablet

(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) 75 mg, 3 times per month	#1) Unknown

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

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

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

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1) MAXALT (RIZATRIPTAN BENZOATE) ; 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	Relevant Med History	Epilepsy (Epilepsy)
Unknown to Ongoing	Relevant Med History	Migraine (Migraine)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San Jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
PV202500064354

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
27-MAY-2025

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

DATE OF THIS REPORT
12-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: PV202500064354

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient also took other concomitant therapy.
The following information was reported: HEADACHE AGGRAVATED (non-serious) with onset 2025, outcome "unknown", described as "headaches had worsened". The action taken for rimegepant was unknown.

Additional Information: The patient reported having started treatment with Nurtec approximately four months ago, initially taking it only during episodes of pain. At the time of the report, her neurologist had prescribed Nurtec every other day due to an increase in the intensity of her headaches. The patient had epilepsy and was under treatment with two anticonvulsants. She mentioned that, over the past month, her headaches had worsened, and during more intense crises, she used sublingual Maxalt, which had caused irritation under her tongue. She indicated that she had not been aware of the patient support plan when she began treatment with Nurtec. Additionally, she noted that pharmacies did not sell her the full box, only individual units. It was noted that, at the time of the report, the patient was not enrolled in the program; however, upon verification before validating the report, it was confirmed that she had already enrolled.

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) Nurtec ODT (RIMEGEPANT)	75 mg, alternate day;	Headache (Headache)	2025 / Unknown;
Orodispersible tablet; Regimen #2	Unknown		Unknown