

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>GUATEMALA</b>	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			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
		Day	Month	Year	Unk	Male	Unk	Day	Month	Year	
			<b>PRIVACY</b>						<b>Unk</b>		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
 Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)  
 headache due to medication abuse and it has gone well [Off label use in unapproved indication]  
 headache due to medication abuse and it has gone well [Drug effective for unapproved indication]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from medical information team.

A male patient received rimegepant (NURTEC ODT), for headache, drug abuse.

(Continued on Additional Information Page)

## 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?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) #1 )	16. ROUTE(S) OF ADMINISTRATION #1 ) Unknown	
17. INDICATION(S) FOR USE #1 ) headache due to medication abuse (Headache)  (Continued on Additional Information Page)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1 ) 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		

## 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. <b>202500097408</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>08-MAY-2025</b>	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 <b>13-MAY-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

13-May-2025 12:33

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.  
The following information was reported: OFF LABEL USE (non-serious), DRUG EFFECTIVE FOR UNAPPROVED INDICATION (non-serious) and all described as "headache due to medication abuse and it has gone well". The action taken for rimegepant was unknown.

Additional information: Patient reported that neurologist indicated this medication for headache due to medication abuse and it has gone well.

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) Orodispersible tablet; Regimen #1	; Unknown	headache due to medication abuse (Headache) headache due to medication abuse (Drug abuse)	Unknown; Unknown