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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	COSTA RICA		PRIVACY		54 Years	Male	Unk		Unk		

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

skin of his mouth broke/skin was weakened [Broken skin]
skin of his mouth broke/skin was weakened [Skin disorder]
felt burning in it (mouth)/ burning and dryness in the oral area [Burning mouth]
burning on the tongue [Burning tongue]
underwent a teeth cleaning, but he noted that he felt an intense pain when applying the toothpaste [Tooth pain]
his hands hurt a lot [Pain in hand]
his skin was dry [Dry skin]
fissures in the anal area [Anal fissure]

(Continued on Additional Information Page)

- ☐ 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) Sutent (SUNITINIB MALATE) Capsule, hard

(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) 50 mg daily (Continued on Additional Information Page)	#1) Oral

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#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.
PV202500033244

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

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

DATE OF THIS REPORT
25-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

food tastes bitter to him [Taste bitter]
his skin acquired a yellowish tone [Yellow skin]
his eyes became dry [Eyes dry]
diarrhea [Diarrhea]
had lost 5 kilos [Weight loss]
poor appetite [Appetite decreased NOS]
burning and dryness in the oral area [Dryness oral]

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

A 54-year-old male patient received sunitinib malate (SUTENT), at 50 mg daily (50 mg daily, every day for 28 days, resting 15 days (take 4 weeks and rest 2 weeks)), oral. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: SKIN WOUND (non-serious), SKIN DISORDER (non-serious), outcome "unknown" and all described as "skin of his mouth broke/skin was weakened"; ORAL DISCOMFORT (non-serious), outcome "unknown", described as "felt burning in it (mouth)/ burning and dryness in the oral area"; TONGUE DISCOMFORT (non-serious), outcome "unknown", described as "burning on the tongue"; TOOTHACHE (non-serious), outcome "unknown", described as "underwent a teeth cleaning, but he noted that he felt an intense pain when applying the toothpaste"; PAIN IN EXTREMITY (non-serious), outcome "unknown", described as "his hands hurt a lot"; DRY SKIN (non-serious), outcome "unknown", described as "his skin was dry"; ANAL FISSURE (non-serious), outcome "unknown", described as "fissures in the anal area"; DYSGEUSIA (non-serious), outcome "unknown", described as "food tastes bitter to him"; YELLOW SKIN (non-serious), outcome "unknown", described as "his skin acquired a yellowish tone"; DRY EYE (non-serious), outcome "unknown", described as "his eyes became dry"; DIARRHOEA (non-serious), outcome "unknown", described as "diarrhea"; WEIGHT DECREASED (non-serious), outcome "unknown", described as "had lost 5 kilos"; DECREASED APPETITE (non-serious), outcome "unknown", described as "poor appetite"; DRY MOUTH (non-serious), outcome "unknown", described as "burning and dryness in the oral area". The action taken for sunitinib malate was unknown. It was unknown if therapeutic measures were taken as a result of skin wound, oral discomfort, tongue discomfort, toothache, pain in extremity, anal fissure, dysgeusia, yellow skin, dry eye, diarrhoea, weight decreased, decreased appetite, dry mouth. Therapeutic measures were not taken as a result of dry skin.

Additional information: the patient reported that when consuming the drug Sutent, the skin of his mouth broke (he felt burning in it) and on the tongue when brushing with toothpaste. He commented that he underwent a teeth cleaning, but he noted that he felt an intense pain when applying the toothpaste. In addition, he mentioned that his skin was weakened, his hands hurt a lot, his skin was dry and had fissures in the anal area. He also said that the food tastes bitter to him, although he had not lost his perception of sweet taste. He indicated that his skin acquired a yellowish tone, his eyes became dry when there were approximately 10 days left before the end of treatment, he had diarrhea, he had lost 5 kilos and had a poor appetite.

Follow-up (20Mar2025): This is a spontaneous follow-up report received from a other HCP, via Program ID 164974:
Updated information: Event 'Burning mouth' was subsumed. New event 'Dryness oral' added.

Follow-up (21Apr2025): This is a spontaneous follow-up report received from a other HCP.
Updated information: Route of administration and Treatment Received was updated for Yellow skin, Burning tongue, Burning mouth, Pain in extremity, Dry skin, Anal fissure, Dysgeusia, Dry eye, Diarrhea, Weight decreased, Decreased appetite, Skin wound, Tooth pain

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) Sutent (SUNITINIB MALATE) Capsule, hard; Regimen #1	50 mg daily, every day for 28 days, resting 15 days (take 4 weeks and rest 2 weeks); Oral	Unknown	Unknown; Unknown