SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
PRIVACY	CR					F				☐ PATIENT DIED
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term] stabbing pain in the heart [Cardiac pain] (10054231 v28.0) - Serious - Not recovered -										☐ LIFE THREATENING ☐ HOSPITALIZATION ☐ DISABILITY OR INCAPACITY ☐ CONGENITAL ANOMALY/BIRTH DEFECT ■ OTHER MEDICALLY IMPORTANT CONDITION ☐ REQUIRED INTERVENTION (MEDICAL DEVICE)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
#1 [Suspect] Fingolimod, 0.5 mg, Capsule (FINGOLIMOD)		☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S) #1 1 dosage form every 1 day(s)	16. ROUTE(S) OF ADMINISTRATION #1 Oral	
17. INDICATION(S) FOR USE #1 Multiple Sclerosis [Multiple sclerosis] (10028245 v28.0)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION ? ☐ YES ☐ NO ☐ NA
18. THERAPY DATES (from/to) #1	19. THERAPY DURATION #1	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

From / To Dates	Description
# 1	Multiple Sclerosis[Multiple sclerosis] (10028245 v28.0) - continue : Yes

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		26. REMARKS
LABORATORIOS STEIN Escazú, Meridiano Building, 5th floor 10203 San José CR		
	24b. MFR CONTROL NO. 2025000290	25b. NAME AND ADDRESS OF REPORTER PRIVACY
24c. DATE RECEIVED BY MANUFACTURER 06-Jun-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ☐ HEALTH PROFESSIONAL ■ OTHER	
DATE OF THIS REPORT 10-Jun-2025	25a. REPORT TYPE ■ INITIAL ☐ FOLLOW UP :	

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case description : This Non-serious Spontaneous case was reported by a non-health care professional in Costa rica (CR) (the primary source) on 06-Jun-2025.

This female patient of unknown age has a medical history of:
1.Multiple Sclerosis (from unk - Contg)
- No concomitant medication was provided.

The patient was treated with the following suspected products:
1.(Suspect) Fingolimod (fingolimod):
- oral, 1 dosage form 1 time(s) per day from an unknown date
for multiple sclerosis.

The patient experienced the following event(s):
1.On an unknown date, in an unspecified time after beginning Fingolimod: stabbing pain in the heart (MedDRA PT: Angina pectoris). The event was assessed as Non-serious (Other medically important condition). For this event, it was unknown if the patient received a corrective treatment.

Event: A patient who, from the moment she took her first capsule of Fingolimod, began to feel a stabbing pain in her heart that did not disappear over the days, says that the nurses did not give it importance because her HR was 63 and that the doctor told her that what she felt was not caused by Fingolimod.

The relevant laboratory test(s) included:
1. on an unknown date, Heart rate : 63

The action(s) taken with the suspected product(s) due to the event(s):
1.Fingolimod: unknown; dechallenge was unknown.
The event(s) outcome was:
1.Stabbing pain in the heart: not recovered/not resolved

The causality assessment was provided as follow:
1.Fingolimod and Cardiac pain:
- Primary reporter: related (Method: Case Source Document).
- Company: possible (Method: Global introspection).
The event was:
- unlisted according to the CDS

At time of this initial report, no more information was provided.

Follow up activities are not possible as there is no consent to contact the reporter of the case. No further information is expected

13. Relevant Tests (date/test/results/units/normal low range/normal high range)

Test date	Test Name	Test results (Code / Numeric Unit / Unstructured)	Low / high
#1 :	Heart rate (10019299 v28.0)	63	/

14-19. Drugs

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	[Suspect] Fingolimod 0.5 mg Capsule (FINGOLIMOD)	1 dosage form every 1 day(s)	UNK	Oral	Multiple Sclerosis [Multiple sclerosis] (10028245 v28.0)		