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	PA				15 Year(s)	F				☐ PATIENT DIED
										☐ LIFE THREATENING
										☐ HOSPITALIZATION
										☐ DISABILITY OR INCAPACITY
										☐ CONGENITAL ANOMALY/BIRTH DEFECT
										☐ OTHER MEDICALLY IMPORTANT CONDITION
										☐ REQUIRED INTERVENTION (MEDICAL DEVICE)

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]
Adult product administered to child [Product use issue] (10076309 v28.0) - Not serious - Recovered -

Difficulty breathing [Difficulty breathing] (10012791 v28.0) - Not serious - Recovered -

chest tightness [Chest tightness] (10008492 v28.0) - Not serious - Recovered -

Adult product administered to child [Adult product administered to child] (10070502 v28.0) - Not serious - Recovered -

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

#1 [Suspect] Monofer, 100, Solution for injection (Ferric derisomaltose)

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1 Please see next page	#1 Intravenous (not otherwise specified)

17. INDICATION(S) FOR USE

#1 Drug use for unknown indication [Drug use for unknown indication] (10057097 v28.0)

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

18. THERAPY DATES (from/to)	19. THERAPY DURATION
#1	#1 30 Minute(s)

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	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
LABORATORIOS STEIN
Escazú, Meridiano Building, 5th floor
10203 San José CR

26. REMARKS

	24b. MFR CONTROL NO.	25b. NAME AND ADDRESS OF REPORTER
	2025000338	PRIVACY
24c. DATE RECEIVED BY MANUFACTURER 01-Jul-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ■ HEALTH PROFESSIONAL ■ OTHER	
DATE OF THIS REPORT 08-Jul-2025	25a. REPORT TYPE ■ INITIAL ☐ FOLLOW UP :	

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case description : This non-serious case received from a healthcare professional via a partner concerns a 15-year-old female patient who started therapy with MONOFER (Ferric derisomaltose), 1000 mg diluted in saline solution 250 cc in 30 minutes on an unknown date due to an unknown indication. Medical history, if any, was not reported. The patient was pre-medicated with chlorotrimeton 10 mg.

On an unknown date, on an unknown time after the infusion of MONOFER had started, the patient developed difficulty breathing and chest tightness. The symptoms subsided after around 20 minutes. Action taken with MONOFER was reported as dose not changed. The outcome of the events was recovered at the time of reporting.

All information provided in the source document has been added to the narrative. No further information is available.
Duplicate numbers : PA-NEBO-700535 (Pharmacosmos).

Section 15. Continued :
Daily dose #1 : 1000 milligram total monofer 1000mg in Saline solution 250cc IV in 30 minutes, single dose.

14-19. Drugs

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	[Suspect] Monofer 100 Solution for injection (Ferric derisomaltose)	1000 milligram total monofer 1000mg in Saline solution 250cc IV in 30 minutes, single dose.	UNK	Intravenous (not otherwise specified)	Drug use for unknown indication [Drug use for unknown indication] (10057097 v28.0)		30 Minute(s)

23. OTHER RELEVANT HISTORY continued

Past Drug Therapy

1 UNK