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	GT				15 Year(s)	F	13	Aug	2025	☐ PATIENT DIED

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]

Product use issue [Product use issue] (10076309 v28.0) - Not serious - Recovered - 13-Aug-2025/13-Aug-2025(1 Day)

Fear [Procedural anxiety] (10075204 v28.0) - Not serious - Recovered - 13-Aug-2025/13-Aug-2025(1 Day)

Fishbane reaction with cougth, blushing of face, arms, feet and neck, respiratory difficulty [Fishbane reaction] (10078603 v28.0) - Not serious - Recovered - 13-Aug-2025/13-Aug-2025(1 Day)

Adult product administered to child [Adult product administered to child] (10070502 v28.0) - Not serious - Recovered - 13-Aug-2025/13-Aug-2025(1 Day)

FISHBANE REACTION [Fishbane reaction] (10078603 v28.0) - Not serious - Recovered - 13-Aug-2025/13-Aug-2025(1 Day)

☐ 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)

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

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1 1000 milligram	#1

17. INDICATION(S) FOR USE

#1 vaginal bleeding [Vaginal bleeding] (10046883 v28.0)

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

18. THERAPY DATES (from/to)	19. THERAPY DURATION
#1 13-Aug-2025/13-Aug-2025	#1 1 Day(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	Vaginal bleeding[Vaginal bleeding] (10046883 v28.0) - continue : No

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.
2025000439

25b. NAME AND ADDRESS OF REPORTER
PRIVACY

24c. DATE RECEIVED BY MANUFACTURER
13-Aug-2025

24d. REPORT SOURCE
■ STUDY ☐ LITERATURE ☐ AUTHORITY
■ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
28-Aug-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) (Batch no. 240909B-5), 1000 mg with duration of 30 minutes on 20250813 due to vaginal bleeding. The patient had a medical history of vaginal bleeding. Concomitant treatment, if any, was not reported.

On 20250813, approximately 5 minutes after the infusion of MONOFER had started, the patient developed a severe cough, blushing of face, arms, feet and neck, respiratory difficulty and fear, symptoms consistent with a Fishbane-type reaction. Therapy with MONOFER was immediately stopped. After approximately 5 minutes the symptoms were with progressive improvement. The colour returned to normal, and the patients breathing improved. After additional 15 minutes where the patient was under observation was the infusion of MONOFER restarted, this time lasting 1 hour. The patient tolerated the infusion of MONOFER with no further adverse symptoms or complications. The infusion of MONOFER was completed. The outcome of the events was recovered on 20250813.

All information provided in the source document has been added to the narrative. No further information is expected.
Duplicate numbers : GT-NEBO-704217 (NEBO), Not Applicable (PSP Solutions).

14-19. Drugs

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	[Suspect] Monofer 100 (Ferric derisomaltose)	1000 milligram	240909B-5		vaginal bleeding [Vaginal bleeding] (10046883 v28.0)	13-Aug-2025/13-Aug-2025	1 Day(s)