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				39 Year(s)	F				☐ PATIENT DIED
7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term] Developed rash on the hands and legs. [Rash] (10037844 v28.0) - Not serious - 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] Monofer, 100, Solution for injection (Ferric derisomaltose)		☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S) #1 1000 milligram	16. ROUTE(S) OF ADMINISTRATION #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) #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

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. 2025000339	25b. NAME AND ADDRESS OF REPORTER PRIVACY
24c. DATE RECEIVED BY MANUFACTURER 01-Jul-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ AUTHORITY ■ HEALTH PROFESSIONAL ■ OTHER	
DATE OF THIS REPORT 16-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 39-year-old female patient who started therapy with MONOFER (ferric derisomaltose), 1000 mg (first dose) on an unknown date due to an unknown indication. The patient was prescribed 2 g of Monofer, divided into 2 doses of 1000 mg. Medical history and concomitant treatment, if any, were not reported.

On an unknown date, 2 days after the infusion of MONOFER had completed, the patient developed developed rash on the hands and legs. Chlorotrimetone and methylprednisolone were administered as treatment. The outcome of the event was recovered on an unknown date.

When the patient was scheduled for the second dose of MONOFER, the patient was premedicated with chlorotrimetone and methylprednisolone, the infusion was completed without reaction.

All information provided in the source document has been added to the narrative. No further information is expected.
Duplicate numbers : PA-NEBO-700519 (NEBO).

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	UNK	Intravenous (not otherwise specified)	Drug use for unknown indication [Drug use for unknown indication] (10057097 v28.0)		