



Report #RMDV9NQ7

Summary

Report Information

Reportum Reference

RMDV9NQ7

Safety Report Version

1

User Details

Bustamante Gómez, Andres Felipe (gestorbayer11@conexus-group.co)

Site

PSDMP-CO-2023-000002 - Betaferon El Salvador

Company aware date

29 Apr 2025

V1 Created At

29 Apr 2025 18:12:11

Reporter Country/location

SV

Language Report Submitted in

Spanish

Client Report Type

Initial Report

Report Categories

Adverse Event

General Info

Suspect products

Betaferon (El Salvador)

Adverse event

INFECCIÓN URINARIA | INTERRUPCIÓN DE TRATAMIENTO

Contact Details

Patient Details

Initials



MGLG

Patient ID

ID 233/ CI 00246437-3

Gender

Female

Is the patient pregnant?

Unknown

Is the patient also the reporter?

Yes

Date of birth

24 Dec 1979

Country/location of Incidence

El Salvador

Additional healthcare professional details

Name

JAIME FERNANDO DELGADO

Does the patient allow that this person can be contacted for further questions about this report?

No

Type

MÉDICO TRATANTE

Event Details

Awareness date of initial or follow-up report

29 Apr 2025

Report version?

Initial Report

INFECCIÓN URINARIA

Onset date

31 Mar 2025 - 14 Apr 2025

Outcome

Recovered completely



INTERRUPCIÓN DE TRATAMIENTO

Onset date

31 Mar 2025 - 14 Apr 2025

Outcome

Recovered completely

Product Details

Suspect products

Betaferon (El Salvador)

Product use

27 Oct 2021 - Ongoing

Batch / Lot Number:

Unknown

Expiry date:

Unknown

Dosage Form

POLVO LIOFILIZADO PARA RECONSTITUIR

What was the dose and how was it administered when the adverse event(s) occurred?

(dose, route of administration, frequency)

1ML

Was the dose changed in response to the adverse event(s)?

No change

Indication for use

Esclerosis múltiple remitente-recurrente

Did the reporter believe the AE was related to the product?

INFECCIÓN URINARIA: No (Unrelated)

INTERRUPCIÓN DE TRATAMIENTO: No (Unrelated)

History

Concomitant medication

Additional products (concomitant or historical) Unknown

Concurrent medical conditions



Other Conditions Unknown

Additional Context

Additional Context

29/ABR/2025

Paciente informa que hace aproximadamente 4 semanas el 31/mar/2025 presentó infección urinaria, motivo por el cual interrumpió la administración de tratamiento Betaferon mientras trataba su infección urinaria (no indica nombre de tratamiento para el manejo de la infección), indica que duró en tratamiento para su infección por 2 semanas hasta el 14/abr/2025 y posteriormente retomó su administración de Betaferon sin ningún inconveniente, no brinda más información.

Is there a product complaint to report?

No

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