Report #P4X5QRS0

Summary

Report Information

Reportum Reference
P4X5QRS0
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
10 Apr 2025
V1 Created At
10 Apr 2025 21:57:09
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

CAMBIO DE TRATAMIENTO

Contact Details

Patient Details

Initials
KMM
Patient ID
ID 398/ CI 05011012-2
Gender
Female
Is the patient pregnant?

Unknown

Is the patient also the reporter?

Yes

Date of birth

30 Jun 1954

Country/location of Incidence

El Salvador

Additional healthcare professional details

Name

JAIME FERNANDO DELGADO MONTAÑO

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

10 Apr 2025

Report version?

Initial Report

CAMBIO DE TRATAMIENTO

Onset date

Feb 2025 - Ongoing

Outcome

Ongoing

Product Details

Suspect products

Betaferon (El Salvador)

Product use

10 Jul 2023 - Feb 2025

Batch / Lot Number:

Unknown

Expiry date:

Unknown

Dosage Form

POLVO LIOFILIZADO PARA RECONSITUIR

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)?

Stopped

Indication for use

Esclerosis múltiple remitente-recurrente

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

CAMBIO DE TRATAMIENTO: Unknown

History

Concomitant medication

Additional products (concomitant or historical) Unknown

Concurrent medical conditions

Other Conditions Unknown

Additional Context

Additional Context

10/ABR/2025
Paciente informa que en cita de control con su médico tratante en feb/2025 (no recuerda fecha exacta), su médico decidió realizar cambio de tratamiento a ocrelizumab, refiere que el cambio del tratamiento se debe a que su enfermedad requiere un tratamiento de mayor eficacia, paciente indica que ya realizó administración de nuevo tratamiento y que las aplicaciones del tratamiento se realizan cada 4 meses, no brinda más información.

Is there a product complaint to report?

No

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