*Farmacovigilancia*

*Fresenius Kabi S.A. Email: vigilanciaecuador@fresenius-kabi.com*

*Km. 4.5 Vía a Durán Tambo T +593 45091003 ext. 129 / out-of-office-hours:*

*092407 Durán, Ecuador +593 968899331 / +593 991502254*

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| --- | --- | --- | --- | --- | --- | --- |
| A. Patient | | | | | | |
| Initials:  \_\_\_\_\_\_\_ | Date of Birth:  \_\_\_\_\_\_\_\_\_ | Age/Age Group:  \_\_\_\_\_\_\_\_\_\_ | Gender:  f  m | Pregnancy:  \_\_\_\_\_week | Weight:  \_\_\_\_\_\_kg | Height:  \_\_\_\_\_\_\_cm |

|  |  |
| --- | --- |
| B. Reporter | |
| Healthcare Professional?  yes  no | |
| If yes, please provide Healthcare Professional details:  Physician  Pharmacist  Others \_\_\_\_\_\_\_\_\_\_  Name:  Address:  Phone number:  E-mail: | If no, please provide consumer/patient details:  Consumer (patient caregiver or other)  Patient  Name:  Address:  Phone number:  E-mail: |
| Consent for Fresenius Kabi to follow-up with consumer/patient for more information?  yes  no  not applicable | |
| Consent for Fresenius Kabi to follow-up with Healthcare Professional?  yes  no  not applicable  Note: please fill the Healthcare Professional contact details above accordingly. | |

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| --- | --- | --- | --- | --- | --- | --- |
| **C. Drug(s)** (Trade name or active substance / dosage form) | Batch/Lot No.**\*** | Route of Administration | Dosage (dose and frequency) | Duration of treatment | | Indication |
| start | end |
| **1** |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |

Suspected causality with drug No.  1  2 3  4 Please tick at least one drug

\*If Batch/Lot no. of Fresenius Kabi suspect drugs is unavailable**,** please fill with appropriate reason(s): “**asked but unknown**”, “**unavailable & consent not received for follow-up**” or “**unavailable & follow-up requested**”.

|  |  |  |
| --- | --- | --- |
| **D. Adverse Reaction(s)** [please describe the reaction(s) and any treatment given]:  Start date:\_\_\_\_\_\_\_\_\_ Stop date:\_\_\_\_\_\_\_\_\_\_\_ Duration:\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Seriousness Criteria of Reaction**(s)  Death (autopsy:  yes  no)  life threatening  hospitalization or prolonged hospitalization  permanent injury or disability  important medical event | **Outcome:**  unknown  complete recovery  recovered with sequelae  not yet recovered  recovering | **Treatment discontinued due to Adverse Reaction**  yes  no  no data  **Improvement after discontinuation**  yes  no  no data  **Reappearance after re-challenge**  yes  no  no data |

In cases of serious Adverse Reactions, it may be helpful to **attach doctor and/or hospital discharge letter**.

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| **E. Medical History and other characteristics** (e.g. underlying and concomitant diseases, other drugs, allergies, smoking, alcohol, liver-/renal deterioration): |
| **F. Relevant Investigations and Laboratory Data** (with date and normal range): |

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| **G. Form completed/filled by**: |
| Name: Date & Signature: |