*Fresenius Kabi Canada Ltd. Email:* *canada\_vigilance@fresenius-kabi.com*

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

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| 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 applicableNote: 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**”.

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| **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):  |

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| **F. Relevant Investigations and Laboratory Data** (with date and normal range): |

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