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| **Type of report:**  ☐ Initial ☐ Follow-up | Reporter signature: |

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| I. REPORTER | | |
| ☐ Physician:  ☐ Specialist: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Other healthcare professional: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Patient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Pharmacist: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Anonymous: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Patient's Approval for Physician / Specialist contact for follow-up  ☐ YES ☐ NO  Reporter's Approval for follow-up  ☐ YES ☐ NO |
| Name of reporter | Institution | | |
| Address | Telephone/Fax/E-mail | | |

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| II. PATIENT | | | | |
| Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ☐ Anonymous ☐ Unknown | | Pregnancy:  ☐ yes ☐ no ☐ not inquired | | Weight (kg): | |
| Date of birth:   |  |  |  | | --- | --- | --- | | dd | mm | yyyy | |  |  |  | | Age: | | Sex:  ☐ male  ☐ female | Height (cm): | |

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| III. ADVERSE DRUG REACTION | | | | | | | | | |
| INDICATE ONLY IF THE REACTION RESULTED IN: | | | | | | | | | |
| ☐ death  ☐ life-threatening condition  ☐ serious medically important event | | | | ☐ permanent or significant impairment/incapacity  ☐ congenital anomaly / birth defect  ☐ initial or prolonged hospitalisation | | | | | |
| ADR onset date: | | |  |  |  | | --- | --- | --- | | dd | mm | yyyy | |  |  |  | | | | ADR resolution date: | | |  |  |  | | --- | --- | --- | | dd | mm | yyyy | |  |  |  | | | |
| ADVERSE DRUG REACTION DIAGNOSIS: | | | | | | | | | |
| DESCRIPTION OF REACTIONS (signs or symptoms): | | | | | | | | | |
| ADVERSE DRUG REACTION TREATMENT: | | | | | | | | | |
| ADR **resolution** following product dechallenge: | | | ☐ yes ☐ no  ☐ not applicable | | ADR **recurrence** following product rechallenge: | | | | ☐ yes ☐ no  ☐ not applicable |
| ADR OUTCOME: | ☐ recovery without sequelae ☐ recovery with sequelae | | | | | ☐ ongoing ☐ death | | ☐ unknown | |

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| IV. SUSPECTED PRODUCTS(S) | | | | | | |
| Suspected product(s) (trade name, INN, manufacturer) | Daily dose | Method of administration | Indication | Start date | Stop date | Actions taken for suspected product **\*** |
|  |  |  |  |  |  |  |

**\*** “Actions taken for suspected product”: **TD**=treatment discontinued **DI**=dose increased **DR**=dose reduced **TC**=treatment completed **NC**=no changes **U**=unknown

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| V. CONCOMITANT PRODUCT(S) | | | | | |
| Concomitant product(s) (trade name, INN, manufacturer) | Daily dose | Method of administration | Indication | Start date | Stop date |
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| VI. MEDICAL HISTORY | |
| other diseases |  |
| drug abuse |  |
| allergies |  |
| smoking |  |
| alcohol |  |
| other |  |

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| VII. DIAGNOSTICS | | |
| Laboratory reports  (incl.: diagnostic imaging, ECG, biopsy etc.) | Date | Report |
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| CAUSAL RELATIONSHIP BETWEEN ADR AND PRODUCT (provided by healthcare professional) | | | |
| ☐ certain | ☐ probable | ☐ possible | ☐ unlikely |

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| VIII. ADDITIONAL INFORMATION |
| (For additional information, with respect to other sections) |

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| TO BE FILLED OUT BY VITAL PHARMA NORDIC |  |
| Reporting date | Vital Pharma Nordic employee (name; signature) |
| |  |  |  | | --- | --- | --- | | dd | mm | yyyy | |  |  |  | |  |