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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 ☐ NOReporter'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:

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| dd | mm | yyyy |
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 | 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: |

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 | ADR resolution date: |

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| 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 **\*** |
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**\*** “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) |
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