SERIOUS ADVERSE EVENT FORM

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| **Study Title:**  **EudraCT number:**  **Site Number:** □□□  **Participant Number:** □□□ | **R&D reference:**  **SAE ID**: □□□ |  |
| DO NOT SEND IDENTIFIABLE DATA  OR SOURCE DOCUMENTS WITH  THIS REPORT |

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| **Initial Report** |  |  | **Follow Up Report** |  |  |

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| **Date of report** | | | | | | | | | | | | | | | | | **D** | | | | | | | | | | | **D** | | | | | | | | | | | | | | | **M** | | | | | | | | | | | | | **M** | | | | | | | **Y** | | | | | | | | | | | **Y** | | | | | | | | | | **Y** | | | | | | **Y** | | | | | | | | | |  | | | | | | | | | |  | | | | | | | | | | |
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| **Subject Details** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Initials | | | | |  | | | | | | |  | | | | | | |  | | | | | | Date of Birth | | | | | | | | | | | | | | | | | | | | | | | | | | **D** | | | **D** | | | **M** | | | | **M** | | | | **Y** | | | | **Y** | | | | | | | | | **Y** | | | | **Y** | | | Gender: | | | | | | Male | | | | | | | | | |  | | | | | | Female | | | | | |  | | | | |  | | |
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| **Serious Adverse Event** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Seriousness criteria (Check all that apply): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Resulted in death | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | Life-threatening | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | Hospitalisation/Prolongation of hospitalisation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |  |
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| Persistent/Significant Disability/Incapacity | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | Congenital anomaly/ Birth defect | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | Other medically important condition | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |  |
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| **If Resulted in Death** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | Date of Death | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Cause of Death: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Cause of Death determined by Autopsy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | **D** | **D** | **M** | | | | **M** | | | | | | | | | **Y** | | | | | **Y** | | | | | **Y** | | | | | | | | | **Y** | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Yes | | | | | | | | | | | |  | | | | | | | | |  | | | No | | | |  | | | | |  | | |
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| Action taken: | | | | | | | | |  | | | | | Drug withdrawn | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | Dose reduced | | | | | | | | | | | | | | | | |  | | | | | | | Dose increased | | | | | | | | | | | | | | | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | | | | | |  | | | | | Dose not changed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | Unknown | | | | | | | | | | | | | | | | |  | | | | | | Not applicable | | | | | | | | | | | | | | | | |  | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Expectedness: | | | | | | | | | | Expected | | | | | | | | | | | | | | | | |  | | | | | | | | |  | | | | | | | | | | | Unexpected | | | | | | | | | | | | |  | | Onset Date: | | | | | | | | | | | | | | | | | | | **D** | | | | | **D** | | | **M** | | | | | **M** | | | | | | | | **Y** | | | | | | **Y** | | | **Y** | | | | | **Y** | | |  | |
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| Relationship to Study Drug: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | None | | | | | | | | | | | |  | | | | | | | |  | | | | | | | Possible | | | | | | | | | | | | | |  | | | | | | Probable | | | | | | | | | | | | | | | | |  | | | | | | | | Definite | | | | | | | | | |  | | | | | | |
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| Severity: | | | |  | | | | | | | | | Mild | | | | | | | | | | | | | | | | | | | |  | | | | | Moderate | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | Severe | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
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| Outcome: | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Recovered | | | | | | | | | | | | | | |  | | | Recovered with sequelae | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | Recovering | | | | | | | | | | |  | | | | | Not recovered | | | | | | | | | | | | | | |  | | | | Unknown | | | | | | | | | | | |  | | | | Fatal | | | | | | | | |  | | | | |  | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Date of Recovery | | | | | | | | | | | | | | | | | | | | | | | D | | | | | | | | D | | | | | | | M | | | | M | | | | | | | | Y | | | | | Y | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| **Event Narrative** | | **Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form** | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
| **Protocol Treatment(s):** | | | | | | | | | | | | | |
| Did the patient take any study medication? | | | | | Yes |  | No | |  |  | | | |
|  | | | | |  |  |  | |  |  | | | |
| Did the subject have to be unblinded? | | | | | Yes |  | No | |  |  | | | |
|  | | | | |  |  |  | |  |  | | | |
| *If yes*, was subject on placebo? | | | | | Yes |  | No | |  |  | | | |
|  | | | | | | | | | |  | | | |
| Study Drug  (insert unknown if still blinded) | Dose | | Frequency | Start Date  (DD/MM/YYYY) | | | | Stop Date  (DD/MM/YYYY) | | | Tick if still ongoing | Route | Batch No |
|  |  | |  |  | | | |  | | |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Medical History**  Provide relevant medical history below or include copy of the Medical History case report form page (if applicable). Include other illnesses present at time of event, previous study emergent adverse events, and pre-existing medical conditions. If additional space is necessary, use further copies of this page. | | | | | | | |
| |  | | --- | |  | | | Check box if a copy of Medical History page of the case report form is included with this report. | | | | | |
| Condition | | | Start Date  (DD/MM/YYYY) | End Date  (DD/MM/YYYY) | Tick if still ongoing | Medication Required | |
| **11** |  | |  |  |  | Yes   |  | | --- | |  | | No   |  | | --- | |  | |
| **22** |  | |  |  |  | Yes   |  | | --- | |  | | No   |  | | --- | |  | |
| **23** |  | |  |  |  | Yes   |  | | --- | |  | | No   |  | | --- | |  | |
| **14** |  | |  |  |  | Yes   |  | | --- | |  | | No   |  | | --- | |  | |
| **25** |  | |  |  |  | Yes   |  | | --- | |  | | No   |  | | --- | |  | |
| **26** |  | |  |  |  | Yes   |  | | --- | |  | | No   |  | | --- | |  | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Concomitant Medications** | | | | | | | | | | |
| Medication | | Start Date  (DD/MM/  YYYY) | End Date  (DD/MM/  YYYY) | Tick if ongoing | Dose | Frequency | Route | Indications | Suspect Drug (tick) | Interaction with study drug (tick) |
| **1** |  |  |  |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |  |  |  |

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| **Relevant Tests List only relevant confirmatory test results for event(s), for example from blood tests, diagnostic imaging** | | | | | | |
| Test | | Date  (DD/MM/YYYY) | Result | Normal Range- Low | Normal Range-High | Comments |
| **11** |  |  |  |  |  |  |
| **22** |  |  |  |  |  |  |
| **23** |  |  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Re-challenge Information** | | | | | | | |
| 1. Did the reaction abate after stopping suspected drug? | Yes |  | No |  | N/A |  |  |
|  |  |  |  |  |  |  |  |
| 2. Did the reaction reappear after re-introduction of suspect drug? | Yes |  | No |  | N/A |  |  |
|  |  |  |  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Primary Source of information** | | | | | | | | | | |
| Name: | | | | | | Email address: | | | | |
| Telephone number: | | | | | | Fax number: | | | | |
|  |  |  |  |  |  | |  |  |  | |
| **Qualification**: | Physician |  | Pharmacist |  | Other Health Professional | |  | Trial Team |  |  |
|  |  |  |  |  |  | |  |  |  | |

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| **To be signed by the Principal Investigator or designee** | | | | | | | | | | | | | | | |
|  | | | |  | | |  |  | | |  |  | | | |
| I am the Principal Investigator | | | | Yes | | |  | No | | |  |  | | | |
| *If No*, Please state designation | | | |  | | | | | | | | | | | |
| **I confirm that this is a SAE** | | | |  | | | | | | | | | | | |
| Name: (PRINT) |  | | | | | | | | | | | | | |  |
| Signature: |  | | | | | | | | | | | | | |  |
|  |  | | | | | | | | | | | | | | |
| Date: | **D** | **D** | **M** | | **M** | **Y** | | | **Y** | **Y** | | | **Y** |  | |
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| **To be signed by the Chief Investigator or designee in the event of a SUSAR** | | | | | | | | | | | | | | | |
|  | | | |  | | |  |  | | |  |  | | | |
| I am the Chief Investigator | | | | Yes | | |  | No | | |  |  | | | |
| *If No*, Please state designation | | | |  | | | | | | | | | | | |
| **I confirm that this is a SUSAR and will be / has been reported to the MHRA and REC** | | | | | | | | | | | | | | | |
| Name: (PRINT) |  | | | | | | | | | | | | | |  |
| Signature: |  | | | | | | | | | | | | | |  |
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| Date: | **D** | **D** | **M** | | **M** | **Y** | | | **Y** | **Y** | | | **Y** |  | |
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| **ALL *SUSAR* REPORTS MUST BE SIGNED AND DATED BY THE CHIEF INVESTIGATOR .**  **PLEASE SIGN & EMAIL ALL SAE AND SUSARREPORTS TO THE TRIAL OFFICE:<*trial email to be inserted>*** | | | |
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| **TRACKING (STU USE ONLY)** | | | |
| **Report received by:** Name: (PRINT) | |  | |
| Signature: | |  | |
|  | |  | |
| Date: | | |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **D** | **D** | **M** | **M** | **Y** | **Y** | **Y** | **Y** |  | | |
| Action Taken: | |  | |