**Did the participant have any Adverse Events (AEs) during the study?  Yes  No *(If yes, list each AE below)***

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| **Adverse Event** | | **Start**  **Date** | | **Stop**  **Date** | | **1Relation** | **2Severity** | **3Expected** | | **4Action Taken** | **5Outcome** | | **6Serious** | **Initials & Date** | |
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| **1Relation to**  **Study Intervention** | **2Severity** | | **3Expected** | | **4 Action Taken Regarding Study Intervention** | | | | **5Outcome of AE**  **(at end of study participation)** | | | **6Serious** | | | |
| 1 = Related  2 = Possibly related  3 = Not related | 1 = Mild  2 = Moderate  3 = Severe | | Y = Yes  N = No | | Examples:  1 = None  2 = Monitor  3 = Con-medication (list drug)  4 = Hold study intervention  5 = Dose reduced  6 = Dose increased  6 = Discontinued study intervention  7 = Other (list intervention) | | | | 1 = Resolved, No Sequelae  2 = AE still present- no treatment  3 = AE still present-being treated  4 = Residual effects present-not treated  5 = Residual effects present- treated  6 = Unknown  7 = Hospitalization  8 = Death | | | Y = Yes  N = No  *If adverse event is serious, please refer to study protocol, IRB, sponsor and/or funding agency for reporting guidelines for Serious Adverse Event (SAE).* | | | |
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