**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 = Related2 = Possibly related 3 = Not related | 1 = Mild2 = Moderate3 = Severe | Y = YesN = No | Examples: 1 = None2 = Monitor3 = Con-medication (list drug)4 = Hold study intervention 5 = Dose reduced6 = Dose increased 6 = Discontinued study intervention 7 = Other (list intervention) | 1 = Resolved, No Sequelae2 = AE still present- no treatment3 = AE still present-being treated4 = Residual effects present-not treated5 = Residual effects present- treated6 = Unknown7 = Hospitalization8 = Death  | Y = YesN = 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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