# Non Serious Adverse Drug Reactions Report

Start Date:2016-10-13 End Date:2016-10-14

| | | | | | | |
|---|---|---|---|---|---|---|
| Study :EMR200136_583 | Investigator :NA | | Country of Investigator :Romania | SiteNo:001 | | |
| Subject No :001-0019 | Subject Initials : | DOB :03/25/1988 | Sex:Female | Race:Caucasian | Height:170(cm) | Weight:58(kg) |
| First administration date of batch : | | | Batch number : | | | |

| Study Drug | Start Date | Dose | Change in Dose |
|---|---|---|---|
| Visit 2 (Month 3) | 06/18/2015 | 9 | |
| Visit 5 (Month12)/Early Termination | | | |
| Visit 3 (Month 6) | 06/18/2015 | 9 | |
| Visit 1/ Baseline (Day 1) | 06/18/2015 | 9 | |
| Visit 4 (Month 9) | 06/18/2015 | 9 | |

| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
|---|---|---|---|---|---|---|
| flu-like symptoms | 06/20/2015 | 09/04/2015 | | Suspected | Mild | |
| Causality Factors | | Action Taken with Study Treatment | Other action taken | Outcome | AE Special Interest | AE dose limiting toxicity |
| None(Othervalue:) | | Not applicable | Concomitant medication | Resolved | | |

Event description:

Subject received concomitant medications:Yes

| Name of medication | Start Date | Ongoing | End Date | Dose | Unit | Frequency |
|---|---|---|---|---|---|---|
| Acetaminophen | 06/18/2015 | | 09/04/2015 | 500 | mg | occasionally |

Does the subject have any relevant past or present medical conditions:No

| Condition | Start Date | Related to study condition | Ongoing |
|---|---|---|---|

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No Data between these 2016-10-13 and 2016-10-14