# Non Serious Adverse Drug Reactions Report

Start Date:2016-07-12 End Date:2016-07-14

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|---|---|---|---|---|---|---|
| Study :EMR200136_583 | Investigator :NA | | Country of Investigator :Romania | SiteNo:001 | | |
| Subject No :001-0006 | Subject Initials : | DOB :05/20/1989 | Sex:Male | Race:Non-Caucasian | Height:176(cm) | Weight:57(kg) |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | | Dose | Change in Dose | | |
| Visit 5 (Month12)/Early Termination | | | | | | |
| Visit 1/ Baseline (Day 1) | 12/19/2014 | | 44 | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| flu-like simptoms | 12/19/2014 | 12/27/2014 | | Suspected | Moderate | |
| Causality Factors | | Action Taken with Study Treatment | Other action taken | Outcome | AE Special Interest | AE dose limiting toxicity |
| None(Othervalue:) | | Not applicable | None | Resolved | | |
| Event description: | | | | | | |
| Subject received concomitant medications | | | | | | |
| Name of medication | Start Date | Ongoing | End Date | Dose | Unit | Frequency |
| Does the subject have any relevant past or present medical conditions:No | | | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing |

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|---|---|---|---|---|---|---|
| Study :EMR200136_583 | Investigator :NA | | Country of Investigator :Romania | SiteNo:001 | | |
| Subject No :001-0017 | Subject Initials : | DOB :07/31/1982 | Sex:Female | Race:Caucasian | Height:165(cm) | Weight:68(kg) |
| First administration date of batch : | | | Batch number : | | | |

| Study Drug | Start Date | Dose | Change in Dose |
|---|---|---|---|
| Visit 2 (Month 3) | 03/06/2015 | 9 | |
| Visit 5 (Month12)/Early Termination | | | |
| Visit 3 (Month 6) | 03/06/2015 | 9 | |
| Visit 1/ Baseline (Day 1) | 03/06/2015 | 9 | |
| Visit 4 (Month 9) | 03/06/2015 | 9 | |

| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity |
|---|---|---|---|---|---|
| inconstant flu-like symptoms | 03/06/2015 | | | 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 | Ongoing | | |

Event description:

Subject received concomitant medications:Yes

| Name of medication | Start Date | Ongoing | End Date | Dose | Unit | Frequency |
|---|---|---|---|---|---|---|
| ciprinol | 06/02/2015 | | 06/04/2015 | 1000 | mg | daily |

Does the subject have any relevant past or present medical conditions:Yes

| Condition | Start Date | Related to study condition | Ongoing |
|---|---|---|---|
| polycystic ovaries | | | Yes |
| ovarian insufficiency | | | Yes |
| dyslipidemia | | | Yes |
| right eye post-traumatic cataract surgery | | | No |
| synovial chist excision | | | No |

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|---|---|---|---|---|---|---|
| Study :EMR200136_583 | Investigator :NA | | Country of Investigator :Romania | SiteNo:002 | | |
| Subject No :002-0001 | Subject Initials : | DOB :08/19/1959 | Sex:Female | Race:Caucasian | Height:156(cm) | Weight:59(kg) |
| First administration date of batch : | | | Batch number : | | | |

| Study Drug | Start Date | Dose | Change in Dose |
|---|---|---|---|
| Visit 5 (Month12)/Early Termination | | | |
| Visit 2 (Month 3) | 02/11/2015 | 8 | |
| Visit 3 (Month 6) | 02/11/2015 | 8 | |
| Visit 1/ Baseline (Day 1) | 02/11/2015 | 8 | |
| Visit 4 (Month 9) | 02/11/2015 | 8 | |

| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity |
|---|---|---|---|---|---|
| Injection site inflammation | 02/11/2015 | | | Suspected | Mild |

| Causality Factors | Action Taken with Study Treatment | Other action taken | Outcome | AE Special Interest | AE dose limiting toxicity |
|---|---|---|---|---|---|
| None(Othervalue:) | Dose not changed | None | Ongoing | | |

Event description:

Subject received concomitant medications

| Name of medication | Start Date | Ongoing | End Date | Dose | Unit | Frequency |
|---|---|---|---|---|---|---|

Does the subject have any relevant past or present medical conditions:Yes

| Condition | Start Date | Related to study condition | Ongoing |
|---|---|---|---|
| Peripheral venous insufficiency | | | No |

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Start Date:2016-07-12 End Date:2016-07-14

| | | | | | | |
|---|---|---|---|---|---|---|
| Study :EMR200136_583 | Investigator :NA | | Country of Investigator :Romania | SiteNo:006 | | |
| Subject No :006-0010 | Subject Initials : | DOB :02/22/1976 | Sex:Female | Race:Caucasian | Height:168(cm) | Weight:66(kg) |
| First administration date of batch : | | | Batch number : | | | |

| Study Drug | Start Date | Dose | Change in Dose |
|---|---|---|---|
| Visit 2 (Month 3) | 04/15/2015 | 8 | |
| Visit 5 (Month12)/Early Termination | | | |
| Visit 3 (Month 6) | 04/15/2015 | 8 | |
| Visit 1/ Baseline (Day 1) | 04/15/2015 | 8 | |
| Visit 4 (Month 9) | 04/15/2015 | 8 | |

| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity |
|---|---|---|---|---|---|
| increased liver enzimes | 07/01/2015 | | | Suspected | Moderate |

| Causality Factors | Action Taken with Study Treatment | Other action taken | Outcome | AE Special Interest | AE dose limiting toxicity |
|---|---|---|---|---|---|
| Disease under study(Othervalue:) | Not applicable | None | Ongoing | | |

Event description:

Subject received concomitant medications:Yes

| Name of medication | Start Date | Ongoing | End Date | Dose | Unit | Frequency |
|---|---|---|---|---|---|---|
| methylprednisolonum | 04/21/2015 | | 04/23/2015 | 1 | grams | qd |
| methylprednisolonum | 01/18/2016 | | 01/20/2016 | 1 | grams | qd |

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

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

# Non Serious Adverse Drug Reactions Report

Start Date:2016-07-12 End Date:2016-07-14

No Data between these 2016-07-12 and 2016-07-14