Non Serious Adverse Drug Reactions Report

Start Date:2016-06-07 End Date:2016-06-08

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:001		
Subject No :001-0003	Subject Initials :	DOB :02/18/1975	Sex:Male	Race:Caucasian	Height:175(cm)	Weight:80(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)	12/19/2014	44	
Visit 3 (Month 6)	12/19/2014	44	
Visit 1/ Baseline (Day 1)	12/19/2014	44	
Visit 4 (Month 9)	12/19/2014	44	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
Flu-like Symptoms	12/22/2014	12/23/2014		Suspected	Mild

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

Non Serious Adverse Drug Reactions Report

Start Date:2016-06-07 End Date:2016-06-08

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 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	Yes		500	mg	inconstancy

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

Condition	Start Date	Related to study condition	Ongoing