Non Serious Adverse Drug Reactions Report

Start Date:2016-09-20 End Date:2016-09-21

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	03/24/2016		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
ciprinol	06/02/2015		06/04/2015	1000	mg	daily
acetaminofen	03/06/2015	Yes		200	mg	per week

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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No Data between these 2016-09-20 and 2016-09-21