Non Serious Adverse Drug Reactions Report

Start Date:2016-06-14 End Date:2016-06-15

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0009	Subject Initials :	DOB :06/30/1965	Sex:Male	Race:Caucasian	Height:183(cm)	Weight:79(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	06/05/2015	9	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	06/05/2015	9	
Visit 1/ Baseline (Day 1)	06/05/2015	9	
Visit 4 (Month 9)	06/05/2016	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
flu-like symptoms	11/09/2015			Suspected	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	Concomitant medication	Ongoing		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Lioresal	01/07/2015	Yes		20	mg	TID
Omnic Tocas	Uk-Unk-2014	Yes		400	mcg	QD
Ibuprofenum	11/09/2015	Yes		400	mg	PRN

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

Condition	Start Date	Related to study condition	Ongoing
benign prostatic hyperplasia			Yes
congenital hydrocephalus			Yes
Depression			Yes