Non Serious Adverse Drug Reactions Report

Start Date:2016-08-09 End Date:2016-08-10

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:006		
Subject No :006-0003	Subject Initials :	DOB :07/16/1984	Sex:Male	Race:Caucasian	Height:182(cm)	Weight:63(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	03/05/2015	8	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	03/11/2015	8	
Visit 1/ Baseline (Day 1)	03/06/2015	8	
Visit 4 (Month 9)	03/11/2015	8	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
increased liver enzymes	09/12/2015	11/14/2015		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 procedure	Resolved		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
tolperison	05/01/2015		05/31/2015	450	miligrams	qd

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

Condition	Start Date	Related to study condition	Ongoing
chronic sinusitis			Yes
pituitary microadenoma			Yes

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No Data between these 2016-08-09 and 2016-08-10