Non Serious Adverse Drug Reactions Report

Start Date:2016-08-03 End Date:2016-08-04

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0003	Subject Initials :	DOB :04/19/1977	Sex:Female	Race:Caucasian	Height:173(cm)	Weight:60(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	05/04/2015	9	
Visit 5 (Month12)/Early Termination			
Visit 3 (Month 6)	05/04/2015	9	
Visit 1/ Baseline (Day 1)	05/04/2015	9	
Visit 4 (Month 9)	05/04/2015	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
elevated liver enzymes	05/30/2015	10/31/2015		Suspected	Moderate

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Concomitant medication(Othervalue:)	Not applicable	Concomitant medication	Resolved		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
Paracetamol	05/04/2015		07/17/2015	500	mg	PRN
LIV 52	05/30/2015		07/19/2015	3	tb	TID
LIV 52	07/20/2015		12/12/2015	6	tb	TID

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

Condition	Start Date	Related to study condition	Ongoing

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Start Date:2016-08-03 End Date:2016-08-04

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:007		
Subject No :007-0006	Subject Initials :	DOB :05/09/1987	Sex:Male	Race:Caucasian	Height:175(cm)	Weight:70(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 2 (Month 3)	05/15/2015	9	
Visit 5 (Month12)/Early Termination			
Visit 1/ Baseline (Day 1)	05/15/2015	9	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
elevated liver enzymes	06/29/2015			Suspected	Moderate	
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:

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
elevated liver enzymes	08/14/2015			Suspected	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Drug withdrawn	Concomitant medication	Ongoing		

Event description:

Subject received concomitant medications:Yes

Name of medication	Start Date	Ongoing	End Date	Dose	Unit	Frequency
LIV 52	06/29/2015	Yes	12/11/2015	6	tablet	tid

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

Condition	Start Date	Related to study condition	Ongoing

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Start Date:2016-08-03 End Date:2016-08-04

No Data between these 2016-08-03 and 2016-08-04