Non Serious Adverse Drug Reactions Report

Start Date:2016-10-14 End Date:2016-10-15

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:005		
Subject No :005-0001	Subject Initials :	DOB :08/27/1996	Sex:Female	Race:Caucasian	Height:169(cm)	Weight:65(kg)
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Visit 5 (Month12)/Early Termination			
Visit 1/ Baseline (Day 1)	02/12/2015	5	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema	04/28/2015	05/30/2015		Suspected	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Drug withdrawn	Led to study termination	Resolved		
Event description:						

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
induration local site injection	04/28/2015	05/30/2015		Suspected	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Drug withdrawn	Led to study termination	Resolved		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

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No Data between these 2016-10-14 and 2016-10-15