

Non Serious Adverse Drug Reactions Report

Start Date:2016-09-04 End Date:2016-09-05

Study :EMR200136_583	Investigator :NA		Country of Investigator :Romania	SiteNo:005		
Subject No :005-0007	Subject Initials :	DOB :05/06/1966	Sex:Female	Race:Caucasian	Height:165(cm)	Weight:70(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)	03/05/2015		9			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
. 1.local erythema at site injection	04/10/2015			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None(Othervalue:)		Drug withdrawn	Led to study termination	Ongoing		
Event description:						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
induration local site injection	03/25/2015			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None(Othervalue:)		Drug withdrawn	Led to study termination	Ongoing		
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:Yes						
Condition				Start Date	Related to study condition	Ongoing
caesarean section						No
uterine fibromas						Yes

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Non Serious Adverse Drug Reactions Report

Start Date:2016-09-04 End Date:2016-09-05

Study :EMR200136_583	Investigator :NA	Country of Investigator :Romania	SiteNo:005			
Subject No :005-0009	Subject Initials :	DOB :04/22/1992	Sex:Female	Race:Caucasian	Height:173(cm) Weight:63(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)	03/26/2015	9				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
local erythema at site injection	06/09/2015			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None(Othervalue:)		Drug withdrawn	Led to study termination	Ongoing		
Event description:						
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
ecchymosis	06/09/2015			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	Ongoing		
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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