

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-21 End Date:2016-04-22

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0071	Subject Initials :LLX	DOB :07/13/1987	Sex:Female	Race:Asian	Height:157cm	Weight:41.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/15/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	06/05/2015		Related	Moderate	
Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
None(Othervalue:)	Not applicable	Led to study termination	Resolved			
Event Description: Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
Laparoscopic pelvic sub sticky, sticky points left fallopian tube surgery.	Uk-Unk-2014	Not on treatment/medication				

21-APR-16

NA/EMR700623-541/C02-0071

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-21 End Date:2016-04-22

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0076	Subject Initials :F-L	DOB :05/15/1987	Sex:Female	Race:Asian	Height:150cm	Weight:51.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/15/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/27/2015	06/03/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event description:Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
Sticky points lower pelvic laparoscopy surgery, tubal surgery.				Uk-Unk-2012	Not on treatment/medication	
Hysteroscopic tubal surgery				Uk-Sep-2014	Not on treatment/medication	

21-APR-16

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