

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-30 End Date:2016-03-31

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0157	Subject Initials :Y-Z	DOB :07/22/1984	Sex:Female	Race:Asian	Height:156cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/25/2015	200				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/10/2015	06/16/2015		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:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition	Start Date	Related to study condition	Ongoing			
HSG: bilateral tubal obstruction	Uk-Unk-2010	Not on treatment/medication				
Laparoscopic Surgery: Tubal clear.	Uk-Unk-2007	Not on treatment/medication				
Ectopic pregnancy laparoscopic surgery: tubal embryo window.	Uk-Jan-2014	Not on treatment/medication				

30-MAR-16

NA/EMR700623-541/C02-0157

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Start Date:2016-03-30 End Date:2016-03-31

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0161	Subject Initials :H-Y	DOB :12/12/1985	Sex:Female	Race:Asian	Height:166cm	Weight:57.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/26/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/10/2015	06/16/2015		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:

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal obstruction	Uk-Unk-2007	Not on treatment/medication	
Laparoscopic tubal surgery sticking points.	Uk-Unk-2007	Not on treatment/medication	
Open left fallopian tube ectopic pregnancy surgery	Uk-Unk-2012	Not on treatment/medication	

31-MAR-16

NA/EMR700623-541/C02-0161

