

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-14 End Date:2016-03-15

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0115	Subject Initials :KJT	DOB :07/02/1988	Sex:Female	Race:Asian	Height:163cm	Weight:52.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/21/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/06/2015	06/12/2015		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 examination: bilateral tubal occlusion	Uk-Unk-2012	Not on treatment/medication				
Laparoscopy surgery: pelvic sticky points, bilateral tubal ostomy + right side mesosalpinx cyst removal.	Uk-May-2015	Not on treatment/medication				

14-MAR-16

NA/EMR700623-541/C02-0115

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Start Date:2016-03-14 End Date:2016-03-15

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0118	Subject Initials :MLF	DOB :08/03/1984	Sex:Female	Race:Asian	Height:160cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/21/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/07/2015	06/12/2015		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 pelvic sticky points, bilateral ovarian drilling	Uk-Unk-2007	Not on treatment/medication	
Cervical biopsy showing inflammation	Uk-Unk-2015	Not on treatment/medication	

14-MAR-16

NA/EMR700623-541/C02-0118

Non Serious Adverse Drug Reactions Report

Start Date:2016-03-14 End Date:2016-03-15

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-049	Subject Initials :PGR	DOB :02/20/1983	Sex:Female	Race:Asian	Height:168cm	Weight:62kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/02/2015	300				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/13/2015	05/29/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Concomitant medication **.Led to study termination	Resolved		
Event Description:albumin treatment and resloved						
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 ovary cystectomy	UK-UNK-2004	Not on treatment/medication				

15-MAR-16

NA/EMR700623-541/k01-049

