

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-01 End Date:2016-04-04

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0174	Subject Initials :YXC	DOB :06/04/2015	Sex:Female	Race:Asian	Height:155cm	Weight:54.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/27/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/12/2015	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			
Laparoscopic surgery: left ovarian endometriosis cystectomy	Uk-Unk-2010	Not on treatment/medication				
HSG: the left fallopian tube obstruction, right fallopian tube inflammation.	Uk-Unk-2012	Not on treatment/medication				
Laparoscopic surgery: pelvic adhesions dissection, left fallopian tube plastic surgery	Uk-Unk-2012	Not on treatment/medication				

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NA/EMR700623-541/C02-0174

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-01 End Date:2016-04-04

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0175	Subject Initials :L-T	DOB :02/15/1989	Sex:Female	Race:Asian	Height:158cm	Weight:40.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/27/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/11/2015	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-Aug-2014	Not on treatment/medication	
Laparoscopy surgery: pelvic adhesions dissection, tubal plastic surgery to repair the left corpus luteum cyst cystectomy,				Uk-Unk-2014	Not on treatment/medication	

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NA/EMR700623-541/C02-0175

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-01 End Date:2016-04-04

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0176	Subject Initials :KBF	DOB :05/19/1986	Sex:Female	Race:Asian	Height:160cm	Weight:57.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/27/2015	200				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/11/2015	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
Tubal examination: passable				Uk-Unk-2008	Not on treatment/medication	
HSG: bilateral tubal occlusion				Uk-Unk-2009	Not on treatment/medication	
Laparoscopy surgery: bilateral tubal repair plastic surgery, pelvic adhesions dissection				Uk-Unk-2011	Not on treatment/medication	
Ectopic pregnancy: open surgery				Uk-Unk-2012	Not on treatment/medication	

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