

Non Serious Adverse Drug Reactions Report

Start Date:2015-06-03 End Date:2015-06-08

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo :C02		
Subject No :C02-0010	Subject Initials :Y-H	DOB :10/18/1985	Sex :Female	Race :Asian	Height :153cm	Weight :47.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/11/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/29/2015	06/02/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
Concomitant medication**(Other value:)		Not applicable	Led to study termination	Resolved		
Event description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions: No						
Condition				Start Date	Related to study condition	Ongoing

04-JUN-15

NA/EMR700623-541/C02-0010

Non Serious Adverse Drug Reactions Report

Start Date:2015-06-03 End Date:2015-06-08

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo :K01		
Subject No :k01-050	Subject Initials :KHG	DOB :04/22/1984	Sex :Female	Race :Asian	Height :150cm	Weight :46kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	05/03/2015		300			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/14/2015	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:)		Dose not changed	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
ovary cystectomy				UK-Jan-2014	Not on treatment/medication	

05-JUN-15

NA/EMR700623-541/k01-050

