

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-18 End Date:2016-05-19

Study :EMR700623-541	Investigator :NA	Country of Investigator :Korea	SiteNo:K01			
Subject No :k01-0059	Subject Initials :LKH	DOB :08/05/1981	Sex:Female	Race:Asian	Height:153cm	Weight:74g
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	06/02/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/13/2015	07/02/2015		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	None	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			

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NA/EMR700623-541/k01-0059

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-18 End Date:2016-05-19

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-036	Subject Initials :JSY	DOB :07/28/1981	Sex:Female	Race:Asian	Height:162cm	Weight:54g
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	03/13/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/24/2015	04/07/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	None	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

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NA/EMR700623-541/k01-036

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-18 End Date:2016-05-19

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-040	Subject Initials :LBH	DOB :03/05/1985	Sex:Female	Race:Asian	Height:164cm	Weight:61g
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	04/06/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	04/15/2015	04/30/2015		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	None	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

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NA/EMR700623-541/k01-040

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-18 End Date:2016-05-19

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:46g
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	

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NA/EMR700623-541/k01-050

