

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-11 End Date:2016-05-12

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|---|-----------------------------------|--------------------------------|---------------------------------|-------------------------|---------------------------|---------------|
| Study :EMR700623-541 | Investigator :NA | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0051 | Subject Initials :yqx | DOB :01/15/1983 | Sex:Female | Race:Asian | Height:154cm | Weight:50.0kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 05/14/2015 | 225 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 05/31/2015 | 06/05/2015 | | 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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement | | | | | | |
| Subject received concomitant medications: | | | | | | |
| Does the subject have any relevant past or present medical conditions:Yes | | | | | | |
| Condition | Start Date | Related to study condition | Ongoing | | | |
| salpingemphraxis,laparoscopic operation | Uk-Unk-2012 | Not on treatment/medication | | | | |

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NA/EMR700623-541/C02-0051

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-11 End Date:2016-05-12

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|--|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0060 | Subject Initials :Y-W | DOB :11/10/1981 | Sex:Female | Race:Asian | Height:150cm | Weight:45.5kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 05/14/2015 | 150 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 05/27/2015 | 06/03/2015 | | 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:Moderate OHSS patients, improved canceled after embryo transfer. | | | | | | |
| 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 pelvic sticking points, ovarian drilling, tubal surgery to clear. | | | | Uk-Unk-2014 | Not on treatment/medication | |

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NA/EMR700623-541/C02-0060

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Start Date:2016-05-11 End Date:2016-05-12

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|---|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0061 | Subject Initials :T-D | DOB :02/15/1988 | Sex:Female | Race:Asian | Height:161cm | Weight:60.0kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 05/14/2015 | 150 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 05/28/2015 | 06/05/2015 | | 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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement | | | | | | |
| Subject received concomitant medications: | | | | | | |
| Does the subject have any relevant past or present medical conditions:Yes | | | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing |
| salpingemphraxis,laparoscopic operation | | | | Uk-Unk-2014 | Not on treatment/medication | |

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NA/EMR700623-541/C02-0061

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|--|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0102 | Subject Initials :HYD | DOB :10/14/1985 | Sex:Female | Race:Asian | Height:163cm | Weight:57.0kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 05/19/2015 | 150 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 06/01/2015 | 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: Moderate OHSS patients, improved canceled after embryo transfer. | | | | | | |
| Subject received concomitant medications: | | | | | | |
| Does the subject have any relevant past or present medical conditions:Yes | | | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing |
| Palace laparoscopy | | | | Uk-Unk-2013 | Not on treatment/medication | |

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NA/EMR700623-541/C02-0102

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|--|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | | Country of Investigator :China | SiteNo:C02 | | |
| Subject No :C02-0136 | Subject Initials :Q-L | DOB :03/28/1984 | Sex:Female | Race:Asian | Height:154cm | Weight:47.0kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 05/22/2015 | 200 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 06/08/2015 | 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: Moderate OHSS patients, improved canceled after embryo transfer. | | | | | | |
| 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 incomplete | | | | Uk-Unk-2014 | Not on treatment/medication | |

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NA/EMR700623-541/C02-0136

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-11 End Date:2016-05-12

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|---|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0137 | Subject Initials :YLF | DOB :11/01/1989 | 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 | 05/22/2015 | 150 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 06/09/2015 | 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: Moderate OHSS occurs canceled embryo transfer, OHSS improvement | | | | | | |
| 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-2014 | Not on treatment/medication | |

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NA/EMR700623-541/C02-0137

Non Serious Adverse Drug Reactions Report

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|--|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | | Country of Investigator :China | SiteNo:C02 | | |
| Subject No :C02-0138 | Subject Initials :TTJ | DOB :06/20/1990 | Sex:Female | Race:Asian | Height:150cm | Weight:41.0kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 05/22/2015 | 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: Moderate OHSS patients, improved canceled after embryo transfer. | | | | | | |
| Subject received concomitant medications: | | | | | | |
| Does the subject have any relevant past or present medical conditions:Yes | | | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing |
| Ectopic pregnancy laparoscopic surgery: the right fallopian tube embryo pelvic sticking points | | | | Uk-Jan-2014 | Not on treatment/medication | |
| Hysteroscopy: endometrial polyps. | | | | Uk-Feb-2015 | Not on treatment/medication | |

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|--|-----------------------|--------------------------------------|------------------------------------|-------------------------------|-------------------------------|------------------------------|
| Study :EMR700623-541 | Investigator :NA | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0153 | Subject Initials :H-H | DOB :07/12/1979 | Sex:Female | Race:Asian | Height:153cm Weight:43.5kg | |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 05/25/2015 | 250 | | | | |
| 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:Moderate OHSS patients, improved canceled after embryo transfer. | | | | | | |
| 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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|---|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | | Country of Investigator :China | SiteNo:C02 | | |
| Subject No :C02-0201 | Subject Initials :J-L | DOB :12/15/1990 | Sex:Female | Race:Asian | Height:168cm | Weight:65kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 09/07/2015 | 225 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 09/26/2015 | 10/02/2015 | | 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:Moderate OHSS occurs canceled embryo transfer, OHSS improvement | | | | | | |
| 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 occlusion | | | | Uk-Unk-2012 | Not on treatment/medication | |
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|---|-----------------------|-----------------------------------|---------------------------------|-------------------------|-----------------------------|---------------------------|
| Study :EMR700623-541 | Investigator :NA | Country of Investigator :China | SiteNo:C02 | | | |
| Subject No :C02-0208 | Subject Initials :MQW | DOB :09/24/1988 | Sex:Female | Race:Asian | Height:156cm | Weight:54.0kg |
| First administration date of batch : | | | Batch number : | | | |
| Study Drug | Start Date | Dose | Change in Dose | | | |
| Gonal-f New Pen Stimulation Treatment | 08/28/2015 | 150 | | | | |
| Adverse Event | Start Date | End Date | Time related to study treatment | Causality to study drug | Severity | |
| OHSS | 09/14/2015 | 09/18/2015 | | 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: Moderate OHSS occurs canceled embryo transfer, OHSS improvement | | | | | | |
| Subject received concomitant medications: | | | | | | |
| Does the subject have any relevant past or present medical conditions:Yes | | | | | | |
| Condition | | | | Start Date | Related to study condition | Ongoing |
| Hysteroscopic resection of endometrial polyps | | | | Uk-Unk-2015 | Not on treatment/medication | |

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NA/EMR700623-541/C02-0208

