

The Safety of Follitropin Alfa/Lutropin Alfa for Stimulation of Follicular Development

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Drug Safety

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Short title (44/50 characters max): *Safety of r-hFSH/r-hLH for Follicular Development*

Electronic Supplementary Material

Electronic Supplementary Material 1. Search terms and standardized MedDRA queries (SMQs) applied to the Merck KGaA Global Safety database for events considered important risks

Safety event	SMQs/PTs applied to database search
OHSS	Specified PTs: 'Abdominal discomfort', 'Abdominal distension', 'Abnormal weight gain', 'Ascites', 'Haemoconcentration', 'Oliguria', 'Ovarian enlargement', 'Ovarian hyperstimulation syndrome', 'Weight increased', 'Ovarian cyst torsion', 'Haemodynamic instability', 'Adnexal torsion', 'Ovarian oedema'
Thromboembolic events, usually with OHSS	Broad scope SMQ: 'Embolic and thrombotic events' Specified PTs: 'Abdominal discomfort', 'Abdominal distension', 'Abnormal weight gain', 'Ascites', 'Haemoconcentration', 'Oliguria', 'Ovarian enlargement', 'Ovarian hyperstimulation syndrome', 'Weight increased', 'Ovarian cyst torsion', 'Haemodynamic instability', 'Adnexal torsion', 'Ovarian oedema'
Hypersensitivity Reactions	SMQs: 'Hypersensitivity', 'Anaphylactic/anaphylactoid shock conditions', 'Angioedema' and 'Anaphylactic reaction broad scope with applied algorithm'
Breast Cancer	Specified PTs: 'Breast cancer'
Ovarian Cancer	'Specified PTs: 'Ovarian cancer'
Uterine Cancer	SMQ: 'Uterine and fallopian tube neoplasms, malignant and unspecified'
Congenital Anomalies	Broad scope SMQ: 'Congenital, familial and genetic disorders'
Malignant Melanoma	Specified PTs: 'Malignant melanoma'

PTs, Preferred terms; SMQs, Standardized MedDRA queries