

## Case Series Drug Analysis Print

**Name: Ulipristal spontaneous UK reports concerning EllaOne/an indication of emergency contraception/30mg dose**

Report Run Date: 07-Aug-2023

Earliest Reaction Date: 20-Jan-2011

MedDRA Version: MedDRA 26.0

Ulipristal spontaneous UK reports concerning EllaOne/an indication of emergency contraception/30mg dose: All UK spontaneous, suspect reports associated with ulipristal and concerning EllaOne/an indication of emergency contraception/30mg dose up to and including 28/07/2023

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	2	0
<b>Blood disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Inner ear signs and symptoms</i>		
Vertigo positional	1	0
<b>Ear disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Anterior pituitary hyperfunction</i>		
Hyperprolactinaemia	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Ocular disorders NEC</i>		
Eye pain	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Photophobia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	3	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	3	0
<b>Eye disorders SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i><b>Diarrhoea (excl infective)</b></i>		
Diarrhoea	17	0
<i><b>Dyspeptic signs and symptoms</b></i>		
Dyspepsia	4	0
<i><b>Faecal abnormalities NEC</b></i>		
Faeces discoloured	1	0
<i><b>Flatulence, bloating and distension</b></i>		
Abdominal distension	12	0
Flatulence	5	0
<i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i>		
Abdominal pain	32	0
Abdominal pain lower	7	0
Abdominal pain upper	12	0
Abdominal tenderness	1	0
Infantile colic	1	0
<i><b>Gastrointestinal disorders NEC</b></i>		
Gastrointestinal disorder	1	0
<i><b>Gastrointestinal signs and symptoms NEC</b></i>		
Abdominal discomfort	5	0
<i><b>Gastrointestinal spastic and hypermotility disorders</b></i>		
Frequent bowel movements	1	0
<i><b>Nausea and vomiting symptoms</b></i>		
Nausea	44	0
Vomiting	14	0
<i><b>Oral dryness and saliva altered</b></i>		
Dry mouth	5	0
<i><b>Oral soft tissue swelling and oedema</b></i>		
Mouth swelling	1	0
<i><b>Umbilical hernias</b></i>		
Umbilical hernia	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>164</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	1	0
Fatigue	20	0
Malaise	12	0
<i><b>Febrile disorders</b></i>		
Pyrexia	3	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	1	0
Feeling abnormal	3	0
Feeling cold	1	0
Feeling of body temperature change	1	0
Thirst	3	0
<i><b>General signs and symptoms NEC</b></i>		
Crying	1	0
Illness	4	0
Influenza like illness	1	0
Peripheral swelling	1	0
<i><b>Interactions</b></i>		
Drug interaction	1	0
<i><b>Oedema NEC</b></i>		
Oedema peripheral	1	0
<i><b>Pain and discomfort NEC</b></i>		
Chest pain	1	0
Discomfort	1	0
Pain	1	0
<i><b>Therapeutic and nontherapeutic responses</b></i>		
Drug ineffective	75	0
Drug tolerance decreased	1	0
Treatment failure	2	0
<b>General disorders SOC TOTAL</b>	<b>135</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Infections</b>		
<i>Candida infections</i>		
Vulvovaginal candidiasis	2	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Urinary tract infections</i>		
Urinary tract infection	2	0
<b>Infections SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	6	0
Exposure via breast milk	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure before pregnancy	2	0
Maternal exposure during pregnancy	20	0
Maternal exposure timing unspecified	2	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	2	0
<i><b>Off label uses</b></i>		
Off label use	1	0
<i><b>Product administration errors and issues</b></i>		
Inappropriate schedule of product administration	21	0
<b>Injuries SOC TOTAL</b>	<b>56</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Reproductive hormone analyses</i>		
Pregnancy test positive	1	0
<i>Urinalysis NEC</i>		
Blood urine present	1	0
<b>Investigations SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	3	0
Food craving	1	0
Increased appetite	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Joint related signs and symptoms</i>		
Arthralgia	1	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	11	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	6	0
Pain in extremity	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>24</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Disturbances in consciousness NEC</b></i>		
Loss of consciousness	1	0
Somnolence	5	0
Syncope	2	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Clumsiness	1	0
Psychomotor hyperactivity	1	0
<i><b>Headaches NEC</b></i>		
Headache	21	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Disturbance in attention	1	0
<i><b>Migraine headaches</b></i>		
Migraine	4	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	25	0
Dizziness postural	1	0
Head discomfort	1	0
Presyncope	1	0
<i><b>Olfactory nerve disorders</b></i>		
Parosmia	1	0
<i><b>Paraesthesias and dysaesthesias</b></i>		
Hyperaesthesia	1	0
Hypoaesthesia	2	0
Paraesthesia	1	0
<i><b>Sensory abnormalities NEC</b></i>		
Dysgeusia	2	0
Taste disorder	1	0
<i><b>Tremor (excl congenital)</b></i>		
Tremor	7	0
<b>Nervous system disorders SOC TOTAL</b>	<b>79</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	3	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	23	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	2	0
Ectopic pregnancy	11	0
Ruptured ectopic pregnancy	3	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Placental abnormalities (excl neoplasms)</i>		
Placenta praevia	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	72	0
Pregnancy on contraceptive	6	0
Pregnancy on oral contraceptive	5	0
Unintended pregnancy	125	0
Unwanted pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>257</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i>Abnormal food elimination</i>		
Self-induced vomiting	1	0
<i>Anxiety symptoms</i>		
Agitation	4	0
Anxiety	13	0
Stress	1	0
Tension	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Paranoia	2	0
Social avoidant behaviour	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
Disorientation	1	0
<i>Depressive disorders</i>		
Depression	4	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	1	0
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	4	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
Emotional disorder	5	0
Mood altered	2	0
<i>Fluctuating mood symptoms</i>		
Mood swings	7	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	4	0
<i>Perception disturbances NEC</i>		
Derealisation	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	2	0
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	1	0
<i>Sexual desire disorders</i>		
Libido decreased	1	0
Libido disorder	1	0
Loss of libido	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
<i>Suicidal and self-injurious behaviour</i>		
Self-injurious ideation	1	0
Suicidal ideation	2	0
<i>Thinking disturbances</i>		
Thinking abnormal	1	0

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
<b>Psychiatric disorders SOC TOTAL</b>	<b>73</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Micturition urgency	1	0
<i>Urinary abnormalities</i>		
Urine odour abnormal	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast discomfort	2	0
Breast pain	7	0
Breast tenderness	7	0
Nipple pain	2	0
<i><b>Cervix disorders NEC</b></i>		
Cervical discharge	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	9	0
Intermenstrual bleeding	5	0
Menstrual disorder	10	0
Menstruation irregular	9	0
Premenstrual pain	1	0
Premenstrual syndrome	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	5	0
Hypomenorrhoea	13	0
Menstruation delayed	105	0
Oligomenorrhoea	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	19	0
Polymenorrhoea	10	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovulation pain	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital pain	2	0
Pelvic discomfort	1	0
Pelvic pain	5	0
Pruritus genital	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	68	0
Vulval disorder	1	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Coital bleeding	1	0
Vaginal discharge	18	0
Vulvovaginal discomfort	3	0
Vulvovaginal dryness	1	0
Vulvovaginal pruritus	3	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>315</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	3	0
Oropharyngeal pain	4	0
Throat irritation	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>

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<b>Skin disorders</b>		
<i><b>Acnes</b></i>		
Acne	5	0
<i><b>Angioedemas</b></i>		
Angioedema	1	0
<i><b>Apocrine and eccrine gland disorders</b></i>		
Cold sweat	1	0
Night sweats	2	0
<i><b>Dermal and epidermal conditions NEC</b></i>		
Dry skin	1	0
Pain of skin	1	0
Papule	1	0
Skin lesion	1	0
<i><b>Dermatitis and eczema</b></i>		
Dermatitis allergic	1	0
Eczema	1	0
Skin irritation	1	0
<i><b>Erythemas</b></i>		
Erythema	3	0
<i><b>Pruritus NEC</b></i>		
Pruritus	4	0
<i><b>Rashes, eruptions and exanthems NEC</b></i>		
Rash	4	0
Rash pruritic	1	0
<i><b>Urticarias</b></i>		
Urticaria	1	0
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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Induced abortions</i>		
Abortion induced	10	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>10</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Peripheral vascular disorders NEC</i>		
Hot flush	11	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1202</b>	<b>0</b>
<b>TOTAL REPORTS</b>	<b>584</b>	