

Case Series Drug Analysis Print
Name: Primodos Product Analysis Print

Report Run Date: 16-Aug-2021
Data Lock Date: 15-Aug-2021 18:30:03
Earliest Reaction Date: 23-Sep-1966
MedDRA Version: MedDRA 24.0
Primodos Product Analysis Print: Primodos Product Analysis Print (PAP)for reports received up to 15/08/2021

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Cardiac disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Bladder disorders congenital</i>		
Congenital bladder anomaly	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	3	1
<i>Cardiac septal defects congenital</i>		
Cardiac septal defect	1	0
Single atrium	1	1
<i>Central nervous system disorders congenital NEC</i>		
Congenital central nervous system anomaly	1	0
Spina bifida	3	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	4	0
Congenital brain damage	2	1
<i>Congenital disorders NEC</i>		
Congenital anomaly	4	2
Heterotaxia	1	0
Multiple congenital abnormalities	1	1
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	1	0
<i>Ear disorders congenital NEC</i>		
Ear malformation	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastrointestinal malformation	1	0
<i>Hearing disorders congenital</i>		
Deafness congenital	3	0
<i>Hepatobiliary abnormalities congenital</i>		
Gallbladder anomaly congenital	1	0
<i>Male reproductive tract disorders congenital</i>		
Hypospadias	1	0
<i>Musculoskeletal and connective tissue disorders of face, neck and jaw congenital</i>		
Cleft lip	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital amputation	1	0
Congenital foot malformation	3	0
Congenital hand malformation	3	0
Developmental hip dysplasia	1	0
Limb malformation	3	0
Limb reduction defect	2	0
Talipes	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Caudal regression syndrome	1	0
Spine malformation	2	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital musculoskeletal anomaly	1	0
<i>Non-site specific muscle disorders congenital</i>		
Congenital muscle absence	1	0
<i>Palate disorders congenital</i>		
Cleft palate	3	0
Congenital disorders SOC TOTAL	54	6

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Ear disorders		
<i>Hearing losses</i>		
Deafness unilateral	1	0
Ear disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal signs and symptoms NEC</i>		
Anal incontinence	1	0
Gastrointestinal disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
General disorders		
<i>Death and sudden death</i>		
Death	2	2
Death neonatal	1	1
<i>General signs and symptoms NEC</i>		
Developmental delay	1	0
<i>Pain and discomfort NEC</i>		
Discomfort	1	0
Pain	3	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse event	1	1
General disorders SOC TOTAL	9	4

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic failure and associated disorders</i>		
Hepatic failure	1	1
Hepatic disorders SOC TOTAL	1	1

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

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Reaction Name	Total	Fatal
Infections		
<i>Lower respiratory tract and lung infections</i>		
Pneumonia	1	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
Infections SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	42	0
Foetal exposure timing unspecified	1	0
Maternal exposure during pregnancy	2	0
Injuries SOC TOTAL	46	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
Limb deformity	1	0
<i>Metabolic bone disorders</i>		
Osteoporosis	1	0
<i>Spine and neck deformities</i>		
Scoliosis	1	0
Muscle & tissue disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Medullary carcinoma of breast	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Renal neoplasms malignant</i>		
Renal cancer	1	0
Neoplasms SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Cortical dysfunction NEC</i>		
Agraphia	3	0
Alexia	2	0
Aphasia	2	0
Dysgraphia	1	0
Dyslexia	3	0
<i>Dyskinesias and movement disorders NEC</i>		
Fine motor skill dysfunction	1	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	2	0
Hemiplegia	1	0
Quadriplegia	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	3	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	4	0
Nervous system disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Complication of pregnancy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	0
Stillbirth	2	0
Pregnancy conditions SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Learning disorders</i>		
Learning disability	3	0
Learning disorder	3	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
Psychiatric disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	1	0
<i>Renal disorders NEC</i>		
Single functional kidney	1	0
<i>Renal failure and impairment</i>		
Chronic kidney disease	1	0
Renal & urinary disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
<i>Neonatal hypoxic conditions</i>		
Cyanosis neonatal	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pneumothorax	1	0
Respiratory disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Mental disability	5	0
Social circumstances SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Uterine therapeutic procedures</i>		
Hysterectomy	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Poor peripheral circulation	1	0
Vascular disorders SOC TOTAL	1	0
TOTAL REACTIONS FOR DRUG	188	11
TOTAL REPORTS	58	
TOTAL FATAL OUTCOME REPORTS		11