



Australian Government
Department of Health
Therapeutic Goods Administration

Case Line Listing

You searched for the following:

Ingredient Name: Pentosan polysulfate sodium

Number of Reports: 33

9 October 2019

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Limitations of the data

This document contains information from reports of adverse events that the TGA has received in relation to therapeutic goods. It does not contain all known information, and an assessment of the safety of a medicine cannot be made based on this information.

Causality

- The reports received by the TGA contain suspected associations that reflect the observations of an individual reporter. The reporter may be a health professional, a sponsor, or a member of the public.
- Adverse events are suspected of being related to a therapeutic good, but this relationship is usually not certain - the symptom may be related to the underlying illness or to other factors.
- There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was taken.

Case no.	Report Date	Onset Date	State	Sex	Age	Outcome	Medicine (Onset Time in Days)	Reaction
130561	28/08/1998	s22		Female	83	s22	Adalat Oros (Nifedipine) - Concomitant (-); Elmiron (Pentosan polysulfate sodium) - Suspect (-); Lasix (furosemide (frusemide)) - Concomitant (-); Sandocal 1000 (Calcium carbonate ; Calcium lactate gluconate) - Concomitant (-); Trade Name Not Specified (Aspirin) - Concomitant (-)	Polyarteritis nodosa
199837	10/08/2004			Female	65		Ducene (Diazepam) - Concomitant (-); Efexor-XR (Venlafaxine hydrochloride) - Concomitant (-); Elmiron (Pentosan polysulfate sodium) - Suspect (0 days); Prodeine Forte (codeine phosphate hemihydrate ; Paracetamol) - Concomitant (-); Tenuate Dospan (Diethylpropion hydrochloride) - Concomitant (-); Vioxx (Rofecoxib) - Concomitant (-)	Depression; Diarrhoea; Nausea
214275	13/12/2005			Female	50		Ditropan (oxybutynin hydrochloride) - Concomitant (-); Elmiron (Pentosan polysulfate sodium) - Suspect (21 days); Norvasc (Amlodipine) - Concomitant (-); Noten (Atenolol) - Concomitant (-); Vagifem (estradiol) - Concomitant (-); Valium (Diazepam) - Concomitant (-)	Cough; Insomnia; Laryngitis; Malaise; Oropharyngeal pain
238883	13/03/2008			Female	79		Elmiron (Pentosan polysulfate sodium) - Suspect (2 days); Trade Name Not Specified (insulin) - Concomitant (-)	Erythema nodosum; Malaise; Oedema peripheral; Pyrexia; Rash papular
306511	07/09/2012			Female	28		Duloxetine (Duloxetine hydrochloride) - Suspect (16 days); Leven ED (ethinylestradiol ; Levonorgestrel) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Concomitant (-); Trade Name Not Specified (buprenorphine hydrochloride) - Suspect (50 days); Valaciclovir (valaciclovir hydrochloride) - Concomitant (-)	Anti-thyroid antibody positive; Decreased appetite; Hot flush; Hyperhidrosis; Nausea; Persistent depressive disorder; Presyncope; Pruritus; Suicidal ideation; Thyroid function test abnormal
336416	14/03/2014			Female	29		Elmiron (Pentosan polysulfate sodium) - Suspect	Accidental overdose;

		s22			s22	(22 days); Mersyndol (codeine phosphate hemihydrate ; doxylamine succinate ; Paracetamol) - Suspect (5 days); Trade Name Not Specified (Alprazolam) - Concomitant (-); Trade Name Not Specified (Diazepam) - Concomitant (-); Trade Name Not Specified (Mirtazapine) - Concomitant (-); Trade Name Not Specified (Pantoprazole) - Concomitant (-); Trade Name Not Specified (Paroxetine) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Concomitant (-); Trade Name Not Specified (amoxicillin trihydrate) - Concomitant (-); Trade Name Not Specified (zolpidem tartrate) - Concomitant (-); Yaz Flex (Drospirenone ; ethinylestradiol) - Suspect (-)	Hepatic failure; Hypophagia
356720	27/03/2015		Female	22		Elmiron (Pentosan polysulfate sodium) - Suspect (-)	Urinary tract infection
362502	26/06/2015		Female	48		Elmiron (Pentosan polysulfate sodium) - Concomitant (-); Topamax (Topiramate) - Suspect (1612 days)	Blepharospasm; Eye pain; Ocular hyperaemia
407568	20/04/2017		Male	84		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (-)	Injection site pain
413275	04/07/2017		Male	84		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (-)	Pain
414073	13/07/2017		Male	56		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (-)	Myalgia; Vomiting
427872	22/02/2018		Female	53		Celebrex (Celecoxib) - Concomitant (-); Coversyl (Perindopril) - Concomitant (-); Trade Name Not Specified (Paracetamol) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (10 days)	Headache
429112	13/03/2018		Male	42		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (-)	Abdominal pain; Angina pectoris; Headache; Nausea
430064	27/03/2018		Female	82		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (11 days)	Thrombocytopenia; Visual impairment

436847	27/06/2018	s22	Female	65	s22	Elmiron (Pentosan polysulfate sodium) - Suspect (-)	Urticaria
436855	27/06/2018		Male	63		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (-)	Myocardial infarction
439062	27/07/2018		Female	82		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (11 days)	Thrombocytopenia
439066	27/07/2018		Female	55		Thyroxine (levothyroxine sodium) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (20 days)	Pruritus; Rash
439125	27/07/2018		Female	57		Diovan (Valsartan) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (7 days)	Decreased appetite; Diarrhoea; Headache; Nausea; Vomiting
440437	14/08/2018		Female	49		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (23 days)	Urticaria
440440	14/08/2018		Female	46		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (-)	Chest pain; Dizziness; Pain in extremity
440527	15/08/2018		Male	55		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (14 days)	Cold sweat; Diarrhoea; Nausea
440741	16/08/2018		Male	54		Trade Name Not Specified (Aspirin) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (0 days); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (10 days); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (3 days); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (7 days)	Abdominal pain; Back pain; Body temperature increased; Dyspepsia
441573	25/08/2018		Male	55		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (14 days)	Cold sweat; Diarrhoea; Headache; Nausea
462205	10/04/2019		Male	59		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (9 days)	Chest pain
469389	26/06/2019		Female	50		Trade Name Not Specified (Chondroitin sulfate ; Glucosamine) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (-)	Menorrhagia; Menstrual disorder
471789	22/07/2019		Female	65		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (24 days)	Arthralgia

475428	30/08/2019	s22	Female	61	s22	Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (7 days)	Headache
476527	12/09/2019		Female	57		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (6 days)	Abdominal pain; Malaise; Musculoskeletal pain
476731	16/09/2019		Female	65		Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (42 days)	Activated partial thromboplastin time prolonged; Thrombin time prolonged
477120	19/09/2019		Female	47		Celebrex (Celecoxib) - Drug Not Administered (-); Disprin (Aspirin) - Drug Not Administered (-); Panadeine Forte (codeine phosphate hemihydrate ; Paracetamol) - Concomitant (-); Phenergan (Promethazine hydrochloride) - Concomitant (-); St John's Wort (Hypericum) - Concomitant (-); Trade Name Not Specified (Glucosamine) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (3 days); Trade Name Not Specified (Product not Coded) - Concomitant (-); Trade Name Not Specified (magnesium) - Concomitant (-); Voltaren (diclofenac potassium ; Diclofenac sodium) - Concomitant (-)	Injection site bruising
478101	01/10/2019		Female	55		Endone (oxycodone hydrochloride) - Concomitant (-); Happy Hormones AUST L 296063 (Actaea racemosa ; Dioscorea oppositifolia ; Glycyrrhiza uralensis ; Gymnema sylvestri ; Lepidium meyenii ; Passiflora incarnata ; Rubus idaeus ; Salvia officinalis ; Silicon dioxide ; Taraxacum officinale ; Trifolium pratense ; Vitex agnus-castus) - Concomitant (-); Thyroxine (levothyroxine sodium) - Concomitant (-); Trade Name Not Specified (Curcumin) - Concomitant (-); Trade Name Not Specified (Paracetamol) - Concomitant (-); Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (10 days)	Arrhythmia; Headache; Muscle spasms; Muscular weakness

478173	02/10/2019	s22	Female	67	s22	Trade Name Not Specified (Pentosan polysulfate sodium) - Suspect (7 days); Trade Name Not Specified (Product not Coded) - Concomitant (-)	Injection site bruising
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