



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	403030	PMT Rescue
ARTG entry for	Medicine Listed	
Sponsor	ATP Science Pty Ltd	
Postal Address	5/63-69 Meakin Road, Meadowbrook, QLD, 4131 Australia	
ARTG Start Date	23/01/2023	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . PMT Rescue

Product Type	Single Medicine Product	Effective Date	23/01/2023
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Permitted Indications

- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood
- Traditionally used in Chinese medicine to regulate/soothe/smooth/disperse the flow of liver-qi/liver
- Maintain/support healthy liver function
- Decrease/reduce/relieve headache symptoms in premenstrual woman
- Maintain/support nervous system health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods in/of blood Deficiency pattern
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods in/of Liver Qi Stagnation pattern
- Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea in/of blood Deficiency pattern
- Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
- Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
- Traditionally used in Western herbal medicine to decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
- Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

- If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Brassica oleracea var. italica sprout Extract dry concentrate	5 mg
Equivalent: Brassica oleracea var. italica (Dry)	100 mg
Brassica oleracea var. italica seed Extract dry concentrate	38.5 mg
Equivalent: Brassica oleracea var. italica (Dry)	385 mg
Bupleurum falcatum root Extract dry concentrate	75 mg
Equivalent: Bupleurum falcatum (Dry)	750 mg
choline bitartrate	367.9 mg
Equivalent: choline	125 mg
Paeonia lactiflora root Extract dry concentrate	75 mg
Equivalent: Paeonia lactiflora (Dry)	1.5 g
pyridoxal 5-phosphate	3.63 mg
Equivalent: pyridoxine	2.47 mg
Vitex agnus-castus fruit Extract dry concentrate	4.44 mg
Equivalent: Vitex agnus-castus (Dry)	199.8 mg

Other Ingredients (Excipients)

croscarmellose sodium
 hypromellose
 magnesium stearate
 maltodextrin
 microcrystalline cellulose
 purified water
 silicon dioxide

Public Summary

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