



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	274356	Thompson's One-A-Day Vitex 1500
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	15/04/2016	
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 . Thompson's One-A-Day Vitex 1500

Product Type	Single Medicine Product	Effective Date	11/08/2021
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Permitted Indications

Maintain/support general health and wellbeing in females
Decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
Decrease/reduce/relieve symptoms of premenstrual tension
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Linked indication - Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
Linked indication - Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
Linked indication - Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
Decrease/reduce/relieve symptoms of premenstrual tension
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve night sweats associated with menopause
Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Vitex agnus-castus fruit Extract dry concentrate **187.5 mg**

Equivalent: Vitex agnus-castus (Dry) 1.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

potable water

potassium acetate

sodium starch glycollate

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