



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	268373	Menopause Formula
ARTG entry for	Medicine Listed	
Sponsor	Wellwisse Pharmaceuticals Pty Ltd	
Postal Address	PO Box 289, Strathfield, NSW, 2135 Australia	
ARTG Start Date	1/02/2016	
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 . Menopause Formula

Product Type	Single Medicine Product	Effective Date	11/12/2020
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Permitted Indications

Traditionally used in Asian medicine to aids/assists with recovery from illness/convalescence

Maintain/support general health and wellbeing

Aids/assists teeth development

Maintain/support bone health

Aids/assists healthy bone development/growth/building

Aids/assists healthy bone development/growth/building

Maintain/support bone mass/density/integrity

Maintain/support bone strength

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life

Maintain/support cardiovascular system health

Traditionally used in Asian medicine to maintain/support healthy appetite

Traditionally used in Asian medicine to relieve digestive discomfort

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support healthy neuromuscular system/function

Maintain/support muscle strength

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Maintain/support neuromuscular function

Maintain/support nervous system health

Maintain/support nervous system function

Traditionally used in Asian medicine to galactagogue/lactagogue/Enhance/improve/promote/increase breast milk production

Traditionally used in Asian medicine to maintain/support breast milk production/lactation

Traditionally used in Asian medicine to expectorant/clear respiratory tract mucous

Indication Requirements

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.



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Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to eating disorders.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet. If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

calcium citrate tetrahydrate	473.93 mg
Equivalent: calcium	100 mg
colecalfiferol	12.5 microgram
Trigonella foenum-graecum seed Extract dry concentrate	300 mg
Equivalent: Trigonella foenum-graecum (Dry)	9.9 g

Other Ingredients (Excipients)

- ascorbyl palmitate
- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- d-alpha-tocopherol
- ethyl acetate
- ethylcellulose
- hypromellose
- iron oxide red
- macrogol 8000

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magnesium stearate
maltodextrin
microcrystalline cellulose
pregelatinised maize starch
silicon dioxide
sucrose
titanium dioxide

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