Public Summary

Summary for ARTG Entry:	226918 Harmony Menopause Max
ARTG entry for	Medicine Listed
Sponsor	Martin & Pleasance Pty Ltd
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia
ARTG Start Date	14/08/2014
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Harmony Menopause Max

Product Type Single Medicine Product **Effective Date** 22/01/2020

Permitted Indications

Traditionally used in Chinese medicine to clear/disperse/expel/dissipate/cool blood-heat

Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness

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

Traditionally used in Chinese medicine to decrease/reduce/relieve muscle pain/ache/soreness

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Chinese medicine to helps decrease/reduce/relieve night sweats associated with menopause

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menopause

Traditionally used in Chinese medicine to decrease/reduce/relieve hot flushes associated with menopause

Traditionally used in Chinese medicine to decrease/reduce/relieve aggression/irritability associated with menopause

Indication Requirements

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

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 chronic fatigue syndrome.

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.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bupleurum falcatum root Extract dry concentrate	**75 mg**
Equivalent: Bupleurum falcatum (Dry)	1.5 g
colecalciferol	**.005 mg**
Paeonia lactiflora root Extract dry concentrate	**214.29 mg**
Equivalent: Paeonia lactiflora (Dry)	3 g
Rehmannia glutinosa root Extract dry concentrate	**416.67 mg**
Equivalent: Rehmannia glutinosa (Dry)	5 g
Vitex agnus-castus fruit Extract dry concentrate	**20 mg**
Equivalent: Vitex agnus-castus (Dry)	200 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
curcumin
dl-alpha-tocopherol
hydrogenated soya oil
hydrolysed gelatin
hypromellose
macrogol 400
magnesium stearate
maize starch
microcrystalline cellulose
silicon dioxide
sucrose

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