



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	389289	MenoBalance
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	31/05/2022	
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 . MenoBalance

Product Type	Single Medicine Product	Effective Date	31/05/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Western herbal medicine to decrease/reduce/relieve excessive perspiration/sweating
- Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating
- Decrease/reduce/relieve spontaneous sweating in peri-menopausal women
- Traditionally used in Western herbal medicine to decrease/reduce/relieve spontaneous sweating
- Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
 - Linked indication - Decrease/reduce/relieve excessive perspiration/sweating
 - Linked indication - Decrease/reduce/relieve disturbed/restless sleep
 - Linked indication - Decrease/reduce/relieve nervous tension/unrest
 - Linked indication - Relieve irritability
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of menopause
- Decrease/reduce/relieve hot flushes associated with menopause
- Maintain/support oestrogen hormone levels in peri-menopausal women
- Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
- Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

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

Actaea racemosa root Extract dry concentrate	40 mg
Equivalent: Actaea racemosa (Dry)	400 mg
Asparagus racemosus root Extract dry concentrate	100 mg
Equivalent: Asparagus racemosus (Dry)	2 g
Rehmannia glutinosa root Extract dry concentrate	350 mg
Equivalent: Rehmannia glutinosa (Dry)	3.5 g
Salvia officinalis leaf Extract dry concentrate	136.67 mg
Equivalent: Salvia officinalis (Dry)	750 mg
Silybum marianum fruit Extract dry concentrate	100 mg
Equivalent: Silybum marianum (Dry)	7 g
Withania somnifera root Extract dry concentrate	150 mg
Equivalent: Withania somnifera (Dry)	1.875 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	150 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	3 g

Other Ingredients (Excipients)

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

glycerol

hypromellose

magnesium stearate

microcrystalline cellulose

povidone

pregelatinised rice starch

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