



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	302168	MenoSupport
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	23/04/2018	
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'.

All products containing *Cimicifuga racemosa* must comply with the following condition of listing by carrying the label statement - 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.

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 . MenoSupport

Product Type	Single Medicine Product	Effective Date	10/08/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve excessive perspiration/sweating

Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest

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 symptoms of 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 mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

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



Australian Government
Department of Health
Therapeutic Goods Administration

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Actaea racemosa rhizome Extract dry concentrate standardised	3.08 mg
Equivalent: Actaea racemosa (Dry)	20 mg
Lepidium meyenii tuber Extract dry concentrate	150 mg
Equivalent: Lepidium meyenii (Dry)	1.5 g
Pinus pinaster stem bark outer Dry	15 mg
Equivalent: Pinus pinaster (Dry)	15000 mg
Salvia officinalis leaf Extract dry concentrate standardised	272.73 mg
Equivalent: Salvia officinalis (Dry)	1.5 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	171.43 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	3 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
povidone

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary