



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	313984	MenoPlus 8-PN
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	7/02/2019	
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 . MenoPlus 8-PN

Product Type	Single Medicine Product	Effective Date	12/04/2023
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Permitted Indications

Relieve weariness/tiredness/fatigue/feeling of weakness

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

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

Maintain/support healthy teeth

Maintain/support bone health

Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Helps enhance/promote/increase body utilisation of (state mineral/vitamin/nutrient)

Maintain/support nervous system function

Traditionally used in Western herbal medicine to soporific/induces sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep

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

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 chronic fatigue syndrome.

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 mental illnesses, disorders or conditions.

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.

Standard Indications

No Standard Indications included on Record

Specific Indications



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Therapeutic Goods Administration

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, enteric coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	100 mg
Asparagus racemosus root Extract dry concentrate	187.5 mg
Equivalent: Asparagus racemosus (Dry)	1125 mg
colecalfiferol	.0125 mg
Humulus lupulus flower Dry	100 mg
Equivalent: Humulus lupulus (Dry)	2000 mg
Lavender Oil	40 mg
Rehmannia glutinosa root Extract dry concentrate	100 mg
Equivalent: Rehmannia glutinosa (Fresh)	1000 mg
Salvia officinalis leaf Extract dry concentrate	300 mg
Equivalent: Salvia officinalis (Dry)	1.5 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	150 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	3 g

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
ethylcellulose
hypromellose
macrogol 400
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
oleic acid
povidone
purified water
silicon dioxide
sodium alginate
stearic acid
strong ammonia solution
sucrose

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