Public Summary

Summary for ARTG Entry:	313984 MenoPlus 8-PN
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	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.

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 . MenoPlus 8-PN

Product Type Single Medicine Product **Effective Date** 20/12/2019

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)

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

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

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.

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

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	**187.5 mg**
colecalciferol	**.0125 mg**
Humulus lupulus	**100 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

Public Summary

sodium alginate

stearic acid

strong ammonia solution

sucrose