Public Summary

Summary for ARTG Entry:	348510 ETHICAL NUTRIENTS CLINICAL ESTROVERA
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	16/11/2020
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 . ETHICAL NUTRIENTS CLINICAL ESTROVERA

Product Type Single Medicine Product **Effective Date** 16/11/2020

Permitted Indications

Maintain/support general health and wellbeing in peri-menopausal women

Help maintain/support emotional wellbeing in peri-menopausal women

Soothe/calm nerves in peri-menopausal women

Decrease/reduce/relieve symptoms of menopause
- Linked indication - Decrease/reduce/relieve disturbed/restless sleep
- Linked indication - Relieve irritability
- Linked indication - Decrease/reduce/relieve muscle pain/ache/soreness
- Linked indication - Decrease/reduce/relieve mild joint pain/soreness
- Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Linked indication - Decrease/reduce/relieve vaginal dryness

Helps reduce occurrence of menopausal symptoms

Decrease/reduce/relieve hot flushes associated with menopause

Maintain/support healthy libido in peri-menopausal women

Maintain/support healthy sexual function in peri-menopausal women

Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Product presentation must only refer to mild joint symptoms.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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, enteric coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Rheum rhaponticum root Extract dry concentrate	**4 mg**
Equivalent: Rheum rhaponticum (Dry)	84 mg

Other Ingredients (Excipients)

croscarmellose sodium
ethylcellulose
hyprolose
hypromellose
medium chain triglycerides
microcrystalline cellulose
oleic acid
purified water
silicon dioxide
sodium alginate
stearic acid
strong ammonia solution