

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 350171 ETHICAL NUTRIENTS CLINICAL FEM FORCE

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 30/11/2020
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 FEM FORCE

Product Type Single Medicine Product Effective Date 30/11/2020

Permitted Indications

Maintain/support energy levels in adolescent females

Maintain/support energy levels

Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate in adolescent females

Relieve weariness/tiredness/fatique/feeling of weakness when dietary intake is inadequate

Aid/assist healthy red blood cell production

Helps maintain/support haemoglobin formation/synthesis

Maintain/support healthy thyroid gland function

Maintain/support healthy thyroid hormones

Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescent females

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to serious cardiovascular conditions.

If product is indicated for supplementation, 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 chronic fatigue syndrome.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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Not for the treatment of iron deficiency conditions (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Capsule, hard **Dosage Form**

Route of Administration Oral

Visual Identification

Active Ingredients

iron amino acid chelate 90 mg Equivalent: iron 18 mg

mecobalamin (co-methylcobalamin) 200.1 microgram potassium iodide 196.21 microgram Equivalent: iodine 150 microgram ubiquinol-10

Other Ingredients (Excipients)

Acacia

ascorbic acid citric acid

dextrin

disodium edetate gellan gum

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

potable water potassium acetate

silicon dioxide

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30 mg