Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 172310 Hormeel SNT

ARTG entry for Medicine Listed

Sponsor Brauer Professional Pty Ltd

Postal Address PO Box 174, GLEN OSMOND, SA, 5064

Australia

ARTG Start Date 17/06/2010
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 . Hormeel SNT

Product Type Single Medicine Product Effective Date 9/07/2019

Permitted Indications

Traditionally used in Homoeopathic medicine to maintain/support female reproductive system health

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Traditionally used in Homoeopathic medicine to maintain/support/regulate healthy menstrual cycle

Indication Requirements

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

Homoeopathic product/preparation or medicine (or words to that effect)

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

Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

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Department of Health

Therapeutic Goods Administration

Pack Size Poison Schedule

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| Cor | npo | ner | ıts |

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Conyza canadensis herb flowering (Homeopathic) 50 mg/g Cyclamen purpurascens root and rhizome (Homeopathic) 50 mg/g Myristica fragrans seed (Homeopathic) 100 mg/g Equivalent: safrole 600 microgram/g Oyster shell (Homeopathic) 100 mg/g sepia (Homeopathic) 50 mg/g Strychnos ignatii seed (Homeopathic) 50 mg/g Equivalent: strychnine (of Strychnos spp.) 1.8 ng/g Viburnum opulus stem bark (Homeopathic) 50 mg/g

Other Ingredients (Excipients)

ethanol

purified water

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