Public Summary

Summary for ARTG Entry:	218522 PERCY'S POWDER
ARTG entry for	Medicine Listed
Sponsor	Health Research Pty Ltd
Postal Address	PO Box 6241, HALIFAX STREET, SA, 5000 Australia
ARTG Start Date	13/12/2013
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 . PERCY'S POWDER

Product Type	Single Medicine Product	**Effective Date**	13/12/2019

Permitted Indications

Helps reduce/decrease free radical damage to body cells
Maintain/support energy production
Helps maintain/support healthy acid/alkali balance in the body
Maintain/support general health and wellbeing
Aid/assist/help/maintain healthy hair follicles
Enhance/improve/promote/increase nail health/strength/thickness
Aid/assist healthy red blood cell production
Helps enhance/promote red blood cell health
Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Enhance/improve/promote immune defence/immunity
Helps enhance/improve/promote/increase healthy muscle tone
Maintain/support nervous system function
Enhance/promote/increase healthy sleep patterns
Maintain/support healthy reproductive hormones

Indication Requirements

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

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

Product presentation must not imply or refer to hormone imbalances.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Not recorded	Not recorded	Not recorded	Child resistant closure	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

dried magnesium sulfate	**419 mg/g**
Equivalent: magnesium	55.8 mg/g
ferrous sulfate	**20 mg/g**
Equivalent: iron	6.5 mg/g
manganese sulfate monohydrate	**20 mg/g**
Equivalent: manganese	6.5 mg/g
potassium iodide	**70 microgram/g**
Equivalent: iodine	53.6 microgram/g
potassium sulfate	**208.5 mg/g**
Equivalent: potassium	93.6 mg/g
selenomethionine	**89.2 microgram/g**
Equivalent: selenium	35.7 microgram/g
zinc sulfate monohydrate	**20 mg/g**
Equivalent: zinc	7.3 mg/g

Other Ingredients (Excipients)

sodium bicarbonate

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