Public Summary

Summary for ARTG Entry:	62225	GRIPP-HEEL
ARTG entry for	Medicine Listed	
Sponsor	Brauer Professional Pty Ltd	
Postal Address	PO Box 174, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	11/11/1997	
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.

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 . GRIPP-HEEL

Product Type	Single Medicine Product	**Effective Date**	11/08/2020

Permitted Indications

Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve the severity of symptoms of common colds and flu

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Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Contains lactose (or words to that effect).

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

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

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	**Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Tablet, uncoated
Route of Administration	Oral
Visual Identification	

Active Ingredients	
Aconitum napellus whole plant (Homeopathic)	**120 mg**
Equivalent: Total alkaloids (of Aconitum spp.)	38.4 ng
Bryonia dioica root (Homeopathic)	**60 mg**
bushmaster snake (Homeopathic)	**60 mg**
Eupatorium perfoliatum herb flowering (Homeopathic)	**30 mg**
phosphorus (Homeopathic)	**30 mg**

Other Ingredients (Excipients)
magnesium stearate