Public Summary

Summary for ARTG Entry:	160013	Galium-Heel S
ARTG entry for	Medicine Listed	
Sponsor	Brauer Professional Pty Ltd	
Postal Address	PO Box 174, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	10/03/2009	
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'.

Sponsors must confirm the absence of aristolochic acids, in all medicines containing herbal material derived from any of the following plant genera - Akebia, Asarum, Bragantia, Clematis, Cocculus, Diploclisia, Menispermum, Saussurea, Sinomenium, Stephania, Vladimiria.
The confirmation must be undertaken by chemical analysis using Liquid Chromatography Mass Spectrometry (LC-MS). The methodology used should adhere to best practice according to contemporary scientific literature.
Confirmatory evidence is to be provided to the Director of Listing Compliance, Complementary and OTC Medicines Branch, prior to supply of each batch in Australia. The evidence submitted to the TGA is to include the certificate of analysis, all relevant details of the methodology, such as analytical method validation data, and the raw results.
All supporting evidence must be approved by the TGA prior to supply of the batch in Australia.

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 . Galium-Heel S

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

Permitted Indications

Traditionally used in Homoeopathic medicine to aids/assists natural body cleansing/detoxification processes

Traditionally used in Homoeopathic medicine to maintain/support healthy lymphatic system

Traditionally used in Homoeopathic medicine to helps stimulate a healthy immune system response

Traditionally used in Homoeopathic medicine to maintain/support kidney function

Indication Requirements

Product presentation must not imply or refer to drugs/alcohol.

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

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must only refer to detoxification in relation to natural body processes.

Standard Indications

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

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

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

Betula pendula sap (Homeopathic)	**50 mg/g**
Equivalent: methyl salicylate	0 ng/g
calcium fluoride (Homeopathic)	**50 mg/g**
caltha palustris herb flowering (Homeopathic)	**50 mg/g**
Clematis recta herb flowering (Homeopathic)	**50 mg/g**
Echinacea angustifolia whole plant (Homeopathic)	**50 mg/g**
Galium aparine herb flowering (Homeopathic)	**40 mg/g**
gold (Homeopathic)	**50 mg/g**
Hedera helix herb top flowering (Homeopathic)	**50 mg/g**
Equivalent: emetine	0 ng/g
honey bee (Homeopathic)	**50 mg/g**
Juniperus communis fruit (Homeopathic)	**50 mg/g**
nitric acid (Homeopathic)	**50 mg/g**
Ononis spinosa herb flowering (Homeopathic)	**50 mg/g**
phosphorus (Homeopathic)	**50 mg/g**
Sedum acre herb flowering (Homeopathic)	**50 mg/g**
Sempervivum tectorum leaf (Homeopathic)	**50 mg/g**
silver (Homeopathic)	**50 mg/g**
Thuja occidentalis twig leafy (Homeopathic)	**50 mg/g**
Urtica urens herb flowering (Homeopathic)	**20 mg/g**

Other Ingredients (Excipients)

ethanol

purified water

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