



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	362074	Henry Blooms Cold Sore Relief
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Ltd	
Postal Address	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
ARTG Start Date	15/04/2021	
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 . Henry Blooms Cold Sore Relief

Product Type	Single Medicine Product	Effective Date	15/04/2021
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Permitted Indications

Helps enhance/promote collagen formation
Maintain/support collagen formation
Maintain/support general health and wellbeing
Maintain/support body tissue repair/regeneration
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps protein synthesis in the body
Helps reduce occurrence of facial cold sores
Decrease/reduce/relieve burning/tingling associated with facial cold sores
Enhance/improve/promote healing of facial cold sores
Decrease/reduce/relieve symptoms of facial cold sores
Maintain/support skin health
Enhance/improve/promote skin repair/healing

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

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Pack Size/Poison information		
Pack Size		Poison Schedule
Components		
1 . Formulation 1		
Dosage Form	Capsule, hard	
Route of Administration	Oral	
Visual Identification		
Active Ingredients		
lysine hydrochloride		625 mg
Equivalent: lysine		500 mg
Other Ingredients (Excipients)		
hypromellose		
magnesium stearate		
microcrystalline cellulose		

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