



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	82621	ENGYSTOL
ARTG entry for	Medicine Listed	
Sponsor	Brauer Professional Pty Ltd	
Postal Address	PO Box 174, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	1/05/2002	
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 . ENGYSTOL

Product Type	Single Medicine Product	Effective Date	27/10/2020
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Permitted Indications

Traditionally used in Homoeopathic medicine to enhance/improve/promote immune defence/immunity

Traditionally used in Homoeopathic medicine to helps enhance/improve/promote immune system function

Helps stimulate a healthy immune system response

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

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

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: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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

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

(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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

Public Summary



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1 . Formulation 1

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

sublimed sulfur (Homeopathic)	37.5 mg
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Vincetoxicum officinale leaf (Homeopathic)	75 mg
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Other Ingredients (Excipients)

magnesium stearate

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