Public Summary

Summary for ARTG Entry:	124349 Mucosa compositum N
ARTG entry for	Medicine Listed
Sponsor	Brauer Professional Pty Ltd
Postal Address	PO Box 174, GLEN OSMOND, SA, 5064 Australia
ARTG Start Date	19/12/2005
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 . Mucosa compositum N

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

Permitted Indications

Traditionally used in Homoeopathic medicine to maintain/support healthy eyesight/vision

Traditionally used in Homoeopathic medicine to maintain/support body mucous membrane health

Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of mild gastritis

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of allergic rhinitis

Traditionally used in Homoeopathic medicine to relieve symptoms of mild upper respiratory tract infections

Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of medically diagnosed cystitis

Indication Requirements

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

Product presentation must only refer to mild gastritis.

Product presentation must only refer to medically diagnosed cystitis.

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 or worsen talk to your medical practitioner.

Label statement: If symptoms persist, talk to your health professional.

Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains lactose (or words to that effect).

If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (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).

(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].

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

Homoeopathic product/preparation or medicine (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

Anemone pulsatilla whole plant (Homeopathic)	**1 mg**
Atropa belladonna whole plant (Homeopathic)	**1 mg**
Equivalent: atropine	0 picogram
Equivalent: Alkaloids calculated as hyoscyamine	.0001 picogram
bushmaster snake (Homeopathic)	**1 mg**
Carapichea ipecacuanha root and rhizome (Homeopathic)	**1 mg**
Equivalent: emetine	.18 picogram
Ceanothus americanus leaf (Homeopathic)	**1 mg**
creosote (Homeopathic)	**1 mg**
hydrastis canadensis root and rhizome (Homeopathic)	**1 mg**
Mandragora officinarum root (Homeopathic)	**1 mg**
Equivalent: hyoscyamine	.0003 picogram
Equivalent: atropine	0 picogram
Equivalent: Hyoscine	0 picogram
Marsdenia cundurango stem bark (Homeopathic)	**1 mg**
Momordica balsamina fruit (Homeopathic)	**1 mg**
Oxalis acetosella herb flowering (Homeopathic)	**1 mg**
phosphorus (Homeopathic)	**1 mg**
Porcine (Homeopathic)	**1 mg**
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potassium dichromate (Homeopathic)	**1 mg**
Semecarpus anacardium fruit (Homeopathic)	**1 mg**
silver nitrate (Homeopathic)	**1 mg**
Strychnos nux-vomica seed (Homeopathic)	**1 mg**
Equivalent: strychnine (of Strychnos spp.)	0 picogram
sublimed sulfur (Homeopathic)	**1 mg**
Veratrum album rhizome (Homeopathic)	**1 mg**
Equivalent: Solanidine	1 ng

Other Ingredients (Excipients)

lactose monohydrate

magnesium stearate