



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	352699	Hilde Hemmes' Herbals Sage 1000 capsule
ARTG entry for	Medicine Listed	
Sponsor	Herbal Supplies Pty Ltd	
Postal Address	PO Box 115, ST AGNES, SA, 5097 Australia	
ARTG Start Date	8/01/2021	
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 . Hilde Hemmes' Herbals Sage 1000 capsule

Product Type	Single Medicine Product	Effective Date	8/01/2021
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Permitted Indications

Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration

Traditionally used in Western herbal medicine to decrease/reduce/relieve excessive perspiration/sweating

Traditionally used in Western herbal medicine to maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to astringent/tightens tissues

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to relieve digestive discomfort

Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness

Traditionally used in Western herbal medicine to lactifuge/reduce breast milk production

Indication Requirements

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

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Salvia officinalis leaf Extract dry concentrate	200 mg
Equivalent: Salvia officinalis (Dry)	1 g

Other Ingredients (Excipients)

calcium hydrogen phosphate

disodium edetate

gellan gum

hypromellose

magnesium stearate

maltodextrin

potable water

potassium acetate

tapioca starch

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