Public Summary

Summary for ARTG Entry: 175934 SELODERMA PSC 400

ARTG entry for	Medicine Listed
Sponsor	Tirsel Pty Ltd
Postal Address	PO Box 1430, FRANKSTON, VIC, 3199 Australia
ARTG Start Date	17/09/2010
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. SELODERMA PSC 400

Product Type Single Medicine Product **Effective date** 17/09/2010

Warnings

For practitioner dispensing only.

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

WARNING: Greater Celandine may harm the liver in some people. Use only under the supervision of a healthcare professional.

Standard Indications

May assist in the management of dry skin.

For the symptomatic relief of dry skin.

Treatment of dry or inflamed skin conditions. [Warning S required]

Specific Indications

No Specific Indications included on Record

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1. Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bupleurum falcatum	**10 mg**

Equivalent: Bupleurum falcatum (Dry)	100 mg
Chelidonium majus	**2.4 mg**
Equivalent: Chelidonium majus (Dry)	12 mg
Choline bitartrate	**150 mg**
Cyanocobalamin	**500 microgram**
Folic acid	**95 microgram**
Lecithin	**50 mg**
Pinellia ternata	**10 mg**
Equivalent: Pinellia ternata (Dry)	50 mg
R,S-alpha Lipoic acid	**25 mg**
Scutellaria baicalensis	**18.75 mg**
Equivalent: Scutellaria baicalensis (Dry)	75 mg
Silybum marianum	**25.14 mg**
Equivalent: Silybum marianum (Dry)	1.7598 g
Taraxacum officinale	**20 mg**
Equivalent: Taraxacum officinale (Dry)	100 mg
Zingiber officinale	**6.8 mg**
Equivalent: Zingiber officinale (Dry)	74.8 mg
Ziziphus jujuba	**12.5 mg**
Equivalent: Ziziphus jujuba (Dry)	50 mg

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