Public Summary

Summary for ARTG Entry:	199643 Niu Pi Xuan Te Xiao Fang a.k.a. Psora-Clear Formula
ARTG entry for	Medicine Listed
Sponsor	Sun Herbal Pty Ltd
Postal Address	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia
ARTG Start Date	31/07/2012
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 . Niu Pi Xuan Te Xiao Fang a.k.a. Psora-Clear Formula

Product Type Single Medicine Product **Effective Date** 24/04/2018

Permitted Indications

Traditionally used in Chinese medicine to invigorate/activate Blood

Traditionally used in Chinese medicine to eliminate/reduce/remove/resolve/dissipate blood-stasis

Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness in/of exterior excess pattern

Traditionally used in Chinese medicine to dispel/expel/disperse/clear external/exogenous heat in/of exterior excess pattern

Traditionally used in Chinese medicine to remove Heat toxin in/of exterior excess pattern

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear exogenous wind in/of exterior excess pattern

Indication Requirements

Product presentation must only refer to detoxification in relation to natural body processes.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to serious cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Angelica polymorpha root Extract dry concentrate	**15.72 mg**
Equivalent: Angelica polymorpha (Dry)	94.32 mg
Campsis grandiflora flower Extract dry concentrate	**9.45 mg**
Equivalent: Campsis grandiflora (Dry)	56.7 mg
Curcuma zedoaria rhizome Extract dry concentrate	**10.5 mg**
Equivalent: Curcuma zedoaria (Dry)	63 mg
Dictamnus desycarpus root bark Extract dry concentrate	**6.3 mg**
Equivalent: Dictamnus desycarpus (Dry)	37.8 mg
forsythia suspensa fruit Extract dry concentrate	**15.72 mg**
Equivalent: forsythia suspensa (Dry)	94.32 mg
Gleditsia sinensis spine Extract dry concentrate	**10.5 mg**
Equivalent: Gleditsia sinensis (Dry)	63 mg
Lonicera japonica flower Extract dry concentrate	**68.19 mg**
Equivalent: Lonicera japonica (Dry)	409.14 mg
Luffa cylindrica fruit vascular tissue Extract dry concentrate	**15.72 mg**
Equivalent: Luffa cylindrica (Dry)	94.32 mg
Paris polyphylla rhizome Extract dry concentrate	**10.5 mg**
Equivalent: Paris polyphylla (Dry)	63 mg
Rehmannia glutinosa root Extract dry concentrate	**15.72 mg**
Equivalent: Rehmannia glutinosa (Dry)	94.32 mg
Saposhnikovia divaricata root Extract dry concentrate	**6.3 mg**
Equivalent: Saposhnikovia divaricata (Dry)	37.8 mg
Smilax glabra rhizome Extract dry concentrate	**52.44 mg**
Equivalent: Smilax glabra (Dry)	314.64 mg
Sparganium stoloniferum rhizome Extract dry concentrate	**10.5 mg**
Equivalent: Sparganium stoloniferum (Dry)	63 mg
Spatholobus suberectus stem Extract dry concentrate	**52.44 mg**
Equivalent: Spatholobus suberectus (Dry)	314.64 mg

Other Ingredients (Excipients)

Agar
carrageenan
hypromellose
sodium citrate dihydrate
soluble maize starch

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