

**Australian Government** 

### **Department of Health**

## Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry:	171421	NOURISH THE BLOOD FORMULA a.k.a. Si Wu Tang	
ARTG entry for	Medicine Listed		
Sponsor	Sun Herbal Pty Ltd		
Postal Address	Unit 5/25 Garema Cct, Kingsgrove, NSW, 2208 Australia		
ARTG Start Date	14/05/2010		
Product Category	Medicine		
Status	Active		
Approval Area	Listed Medicines	5	

#### 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

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1 . NOURISH THE BLOOD FORMULA a.k.a. Si Wu Tang					
Product Type	Single Medicine Product	Effective Date	4/05/2018		
Permitted Indication	ns				
Traditionally used in	Chinese medicine to invigorate/activate E	Blood			
Traditionally used in	Chinese medicine to tonify/nourish/streng	gthen/replenish Blood			
Indication Requiren	nents				
you.	is used on medicine label, label statemen n must not imply or refer to serious cardic		ofessional if you are unsure if this medicine is right for		
Standard Indication	IS				
No Standard Indication	ons included on Record				
Specific Indications	3				
No Specific Indication	ns included on Record				
Warnings					
For practitioner dispe	ensing only.				
Additional Product	information				
Pack Size/Poison in	formation				
Pack Size		Poison Schedule			
Components					
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Therapeutic Goods Administration

1. Formulation 1				
Dosage Form	Capsule, hard			
Route of Administration	Oral			
Visual Identification				
Active Ingredients				
Angelica polymorpha root	81.9 mg			
Equivalent: Angelica polyr	491.4 mg			
Ligusticum striatum rhizome Extract dry concentrate		56.4 mg		
Equivalent: Ligusticum stri	iatum (Dry)	338.4 mg		
Paeonia lactiflora root Ext	ract dry concentrate	81.9 mg		
Equivalent: Paeonia lactifle	ora (Dry)	491.4 mg		
Rehmannia glutinosa root Extract dry concentrate		81.9 mg		
Equivalent: Rehmannia gli	utinosa (Dry)	491.4 mg		
Other Ingredients (Excipie	ents)			
Agar				
carrageenan				
hypromellose				
sodium citrate dihydrate				

soluble maize starch

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