

Australian Government

# **Department of Health and Aged Care**

Therapeutic Goods Administration

**Public Summary** 

Summary for ARTG Entry:	215427	Clear Skin
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pt	y Ltd
Postal Address	PO Box 3143, KI Australia	RRAWEE, NSW, 2232
ARTG Start Date	27/09/2013	
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 . Clear Skin							
Product Type	Single Medicine Product	Effective Date	16/09/2022				
Permitted Indicatio	ns						
Antioxidant/Reduce	free radicals formed in the body						
Maintain/support col	lagen formation						
Traditionally used in	Western herbal medicine to alterative/blood c	leanser/depurative/purifier					
Traditionally used in Western herbal medicine to maintain/support waste elimination via the skin							
Maintain/support connective tissue health							
Aid/assist/helps con	Aid/assist/helps connective tissue production/formation						
Maintain/support immune system health							
Maintain/support healthy immune system function							
Maintain/support immune system to fight illness							
Traditionally used in	Western herbal medicine to relieve symptoms	s of acne					
Traditionally used in	Western herbal medicine to relieve minor skin	eruptions					
Traditionally used in	Western herbal medicine to decrease/reduce/	relieve symptoms of mild eczem	a/dermatitis				
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of boils							
Maintain/support skin health							
Traditionally used in Western herbal medicine to maintain/support skin health							
Traditionally used in Western herbal medicine to vulnerary/wound healing							
Maintain/support wo	und healing						
Traditionally used in Western herbal medicine to enhance/promote/increase urine output							
Indication Requirer	ments						
Product presentatio	n must not imply or refer to serious immunolog	gical diseases.					
Label statement: If symptoms persist, talk to your health professional.							
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.							
Product presentatio	Product presentation must not imply or refer to drugs/alcohol.						
Product presentatio	Product presentation must only refer to mild eczema.						

Product presentation must not imply or refer to kidney disease.

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

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Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

# Warnings

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

#### **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						
Arctium lappa root Extract	t dry concentrate		150 mg			
Equivalent: Arctium lappa	(Dry)		1.5 g			
Calendula officinalis flowe	er Extract dry concentrate		50 mg			
Equivalent: Calendula offic	cinalis (Dry)		500 mg			
Echinacea purpurea whole	e plant Extract dry concentrate		53.333 mg			
Equivalent: Echinacea pur	purea (Dry)		800 mg			
pyridoxine hydrochloride			25 mg			
Equivalent: pyridoxine			20.6 mg			
retinol acetate			.5307 mg			
Equivalent: vitamin A			.4499 mg			
Rumex crispus root Extrac	ct dry concentrate		75 mg			
Equivalent: Rumex crispus	s (Dry)		600 mg			
zinc amino acid chelate			60 mg			
Equivalent: zinc			12 mg			
Other Ingredients (Excipie	ents)					
Acacia						
calcium hydrogen phosph	ate dihydrate					
colloidal anhydrous silica						
copovidone						

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microcrystalline cellulose spray-dried glucose syrup

crospovidone dl-alpha-tocopherol glucose monohydrate hypromellose macrogol 400 magnesium stearate maize starch

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