

**Australian Government** 

# **Department of Health**

# Therapeutic Goods Administration

**Public Summary** 

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. Detox & Liver Support Product Type Single Medicine Product Effective Date 7/02/2022 Permitted Indications Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier Traditionally used in Western herbal medicine to aids/assists natural body cleansing/detoxification processes Traditionally used in Western herbal medicine to maintain/support natural body cleansing/detoxification processes

Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes

Traditionally used in Western herbal medicine to aids/assists excretion of metabolic waste products

Traditionally used in Western herbal medicine to temporarily relieve mild fluid retention

Traditionally used in Western herbal medicine to maintain/support healthy lymphatic system

Traditionally used in Western herbal medicine to helps enhance/promote healthy liver function

Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver

Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic

Traditionally used in Western herbal medicine to maintain/support liver health

Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of acne

Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of eczema/dermatitis

# Indication Requirements

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

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 liver disease, such as cirrhosis, hepatitis.

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

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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

Label statement: If fluid retention persists, seek medical advice (or words to that effect).

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

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

Product presentation must only refer to mild fluid retention.

## **Standard Indications**

No Standard Indications included on Record

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Therapeutic Goods Administration

Specific Indications

Specific Indicati	ons					
No Specific Indica	ations included on Record					
Warnings						
No Warnings incl	uded on Record					
Additional Prod	uct information					
Container inform	nation					
Туре	Material	Life Time	Temperature	Closure	Conditions	
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded	
Pack Size/Poiso	n information					
Pack Size Poison Scho				dule		
Components						
1. Formulatio	n 1					
Dosage Form	Capsule, ha	ırd				
Route of Admi	inistration Oral					
Visual Identifie	cation					
Active Ingredi	ents					
Active Ingredients Arctium lappa root Extract dry concentrate 30 mg					1	
	rctium lappa (Dry)			600 mg		
Bupleurum falcatum root Extract dry concentrate				62.5 mg		
Equivalent: B	upleurum falcatum (Dry)			1.25 g		
Chlorella vulg	aris whole plant Powder			250 mg		
Cynara scolymus leaf Extract dry concentrate				62.5 mg		
Equivalent: C	synara scolymus (Dry)			1.25 g		
Galium aparine herb Extract dry concentrate				37.5 n	ng	
Equivalent: Galium aparine (Dry)				750 m	Ig	
Schisandra chinensis fruit Extract dry concentrate				80 mg	I	
Equivalent: Schisandra chinensis (Dry)				2 g		
Taraxacum officinale leaf Extract dry concentrate				100 mg		
Equivalent: T	araxacum officinale (Dry)			3 g		
Other Ingredie	ents (Excipients)					
ascorbyl palm	itate					
calcium hydro	gen phosphate dihydrate	•				
colloidal anhy	drous silica					
hypromellose						
maltodextrin						

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microcrystalline cellulose

potable water

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