

**Australian Government** 

### **Department of Health**

## Therapeutic Goods Administration

**Public Summary** 

Jonations

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 . Eagle Curcuvestin Complex						
Product Type	Single Medicine Product	Effective Date	11/02/2021			
Permitted Indications						
Antioxidant/Reduce	free radicals formed in the body					
Helps reduce/decre	elps reduce/decrease free radical damage to body cells					
Maintain/support natural liver cleansing/detoxification processes						
Maintain/support ge	Maintain/support general health and wellbeing					
Anti-inflammatory/re	elieve inflammation					
Decrease/reduce/re	lieve mild rheumatic aches and pains					
Decrease/reduce/re	lieve symptoms of mild arthritis/mild osteoarthri	tis				
Linked indication - Decrease/reduce/relieve mild joint aches and pains Linked indication - Decrease/reduce/relieve mild joint pain/soreness Linked indication - Decrease/reduce/relieve mild joint inflammation/swelling Linked indication - Decrease/reduce/relieve mild joint stiffness						
Maintain/support joint health						
Maintain/support joint mobility/flexibility						
Maintain/support healthy liver function						
Maintain/support liver health						

#### Indication Requirements

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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

Product presentation must only refer to mild rheumatic aches/pains.

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

Product presentation must only refer to mild joint symptoms.

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

### **Standard Indications**

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No Standard Indications included on Record

Specific Indications						
No Specific Indications include	d on Record					
Warnings						
If symptoms persist consult your healthcare practitioner (or words to that effect).						
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						
Acacia catechu stem heart	Acacia catechu stem heartwood Dry		50 mg			
Equivalent: catechin and e	picatechin (of Acacia catechu) ()		32.5 mg			
Equivalent: Acacia catechu	ı (Dry)		1000 mg			
Curcuma longa rhizome Ex	tract dry concentrate standardised		111 mg			
Equivalent: Curcuma longa			18315 mg			
Scutellaria baicalensis roo	-		200 mg			
Equivalent: Scutellaria baio			4000 mg			
Other Ingredients (Excipie	nts)					
calcium hydrogen phospha	ate dihydrate					
colloidal anhydrous silica						
croscarmellose sodium						
crospovidone hypromellose						
lecithin						
magnesium stearate						
microcrystalline cellulose						
sodium starch glycollate						

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