

### **Australian Government**

## **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 324630 CurcuSolv 500mg

ARTG entry for Medicine Listed

Sponsor Factors Group Australia Pty Ltd

Postal Address Unit B 10-16 South Street, Rydalmere, NSW, 2116

Australia

ARTG Start Date 10/10/2019
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 . CurcuSolv 500mg

Product Type Single Medicine Product Effective Date 27/03/2025

# Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Anti-inflammatory/relieve inflammation

Decrease/reduce/relieve mild joint aches and pains

Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis

Helps maintain/supports healthy joint cartilage growth/development/production

Maintain/support joint mobility/flexibility

### **Indication Requirements**

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

Product presentation must only refer to mild joint symptoms.

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

### **Standard Indications**

No Standard Indications included on Record

### **Specific Indications**

No Specific Indications included on Record

# Warnings

In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.

### **Additional Product information**

# Pack Size/Poison information

Pack Size Poison Schedule

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# Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Ora

**Visual Identification** 

**Active Ingredients** 

curcumin 50 mg dimethyl sulfone 300 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

glycerol

hyprolose

hypromellose

magnesium stearate

microcrystalline cellulose

silicon dioxide

stearic acid

Steviol glycosides

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