



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	127311	Active Elements Active 7.1 Tablets
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Active Elements Pty Ltd	
<b>Postal Address</b>	50 Fairbairn Avenue, MOUNT MARTHA, VIC, 3934 Australia	
<b>ARTG Start Date</b>	26/04/2006	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Active Elements Active 7.1 Tablets

Product Type	Single Medicine Product	Effective Date	4/03/2021
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#### Permitted Indications

- Traditionally used in Homoeopathic medicine to maintain/support natural liver cleansing/detoxification processes
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve watery eyes/excessive lacrimation
- Traditionally used in Homoeopathic medicine to temporarily relieve mild fluid retention
- Maintain/support general health and wellbeing
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild mouth ulcers
- Traditionally used in Homoeopathic medicine to anti-inflammatory/relieve inflammation
- Maintain/support blood health
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal cramping
- Traditionally used in Homoeopathic medicine to maintain/support liver health
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of hayfever
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle cramps
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild nerve pain/neuralgia
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve menstrual spasms/cramps
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve vaginal dryness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve bronchial mucous congestion
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common colds and flu
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of head cold
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Traditionally used in Homoeopathic medicine to loosen respiratory tract mucous
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve mild swelling of the glands associated with common cold
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common cold
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild throat infection
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild tonsillitis
- Traditionally used in Homoeopathic medicine to relieve symptoms of acne
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of dandruff

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Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild eczema/dermatitis

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of facial cold sores

#### Indication Requirements

- Product presentation must not imply or refer to recurrent or persistent mouth lesions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- Product presentation must only refer to mild eczema.
- Label statement: If fluid retention persists, seek medical advice (or words to that effect).
- Product presentation must not imply or refer to cardiovascular or renal conditions.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Product presentation must only refer to mild tonsillitis.
- Respiratory tract infections must be qualified by 'mild'.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- Product presentation must only refer to mild mouth ulcers.
- 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 fluid retention.
- Product presentation must only refer to mild nerve pain/neuralgia.
- Product presentation must only refer to mild gland swelling.
- Product presentation must not imply or refer to drugs/alcohol.
- Product presentation must only refer to detoxification in relation to natural body processes.
- Product presentation must not imply or refer to serious infections.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

- Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
- Not for the treatment of iron deficiency conditions (or words to that effect).
- Contains homoeopathic ingredients.
- If fluid retention persists, seek medical advice (or words to that effect).
- Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
- If coughing persists consult your doctor (or a healthcare professional) (or words to that effect).
- Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children.
- If symptoms persist consult your healthcare practitioner (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information

Pack Size	Poison Schedule
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#### Components

##### 1 . Formulation 1

Dosage Form	Tablet, uncoated
Route of Administration	Oral

#### Visual Identification

#### Active Ingredients

calcium sulfate dihydrate	15 mg
Equivalent: calcium	3.49 mg
calcium sulfate dihydrate (Homeopathic)	5 microgram



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<b>ferrous phosphate octahydrate (Homeopathic)</b>	<b>5 microgram</b>
Equivalent: iron	0 mg
<b>iron phosphate</b>	<b>10 mg</b>
Equivalent: iron	3.34 mg
<b>magnesium phosphate pentahydrate (Homeopathic)</b>	<b>5 microgram</b>
<b>magnesium phosphate pentahydrate</b>	<b>70 mg</b>
Equivalent: magnesium	14.46 mg
<b>potassium chloride (Homeopathic)</b>	<b>5 microgram</b>
Equivalent: potassium	0 mg
<b>potassium sulfate</b>	<b>50 mg</b>
Equivalent: potassium	22.44 mg
<b>potassium sulfate (Homeopathic)</b>	<b>5 microgram</b>
<b>sodium chloride (Homeopathic)</b>	<b>5 microgram</b>
<b>sodium sulfate (Homeopathic)</b>	<b>5 microgram</b>
<b>sodium sulfate</b>	<b>100 mg</b>
Equivalent: sodium	32.37 mg

**Other Ingredients (Excipients)**

Acacia  
carmoisine  
colloidal anhydrous silica  
inulin  
magnesium stearate  
microcrystalline cellulose  
potassium chloride  
soy polysaccharide  
tapioca starch

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