



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

## Public Summary

<b>Summary for ARTG Entry:</b>	127004	Active Elements Active 4.2 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>	18/04/2006	
<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 4.2 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 relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Homoeopathic medicine to helps temporarily relieve light sensitivity
- 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 halitosis/bad breath
- Traditionally used in Homoeopathic medicine to relieve mild tissue oedema
- Traditionally used in Homoeopathic medicine to aid/assist/helps in the management of food cravings
- Traditionally used in Homoeopathic medicine to aid/assist/helps in the management of carbohydrate cravings
- Traditionally used in Homoeopathic medicine to aid/assist/helps in the management of sugar cravings
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal cramping
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal spasm
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of nervous indigestion
- Traditionally used in Homoeopathic medicine to maintain/support healthy liver function
- 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 helps decrease/reduce/relieve mild muscle spasms/twitches
- Traditionally used in Homoeopathic medicine to relieve irritability
- Traditionally used in Homoeopathic medicine to soothe/calm nerves
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Homoeopathic medicine to decrease/reduce mental/cognitive fatigue

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Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms  
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild migraine symptoms  
 Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of sensitivity to light/sound associated with mild migraine  
 Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of mild tension headache  
 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 loosen respiratory tract mucous  
 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 only refer to mild fluid retention.  
 Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.  
 Product presentation must only refer to mild anxiety.  
 Product presentation must only refer to mild migraine.  
 Product presentation must only refer to mild eczema.  
 Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.  
 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 chronic fatigue syndrome.  
 Label statement: If fluid retention persists, seek medical advice (or words to that effect).  
 Product presentation must only refer to mild nerve pain/neuralgia.  
 Product presentation must only refer to detoxification in relation to natural body processes.  
 Product presentation must not imply or refer to gastro oesophageal reflux disease.  
 Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.  
 Product presentation must not imply or refer to drugs/alcohol.  
 Product presentation must not imply or refer to cardiovascular or renal conditions.  
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist consult your healthcare practitioner (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).  
 Contains homoeopathic ingredients.  
 If fluid retention persists, seek medical advice (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, uncoated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>dibasic potassium phosphate</b>	<b>60 mg</b>
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Equivalent: potassium	26.94 mg
<b>dibasic potassium phosphate (Homeopathic)</b>	<b>5 microgram</b>
<b>magnesium phosphate pentahydrate</b>	<b>100 mg</b>
Equivalent: magnesium	20.66 mg
<b>magnesium phosphate pentahydrate (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>200 mg</b>
Equivalent: sodium	64.74 mg

**Other Ingredients (Excipients)**

Acacia  
calcium phosphate  
colloidal anhydrous silica  
inulin  
magnesium stearate  
microcrystalline cellulose  
soy polysaccharide  
tapioca starch

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