



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	127009	Active Elements Active 2.3 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 2.3 Tablets

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	26/02/2021
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### Permitted Indications

Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Homoeopathic medicine to helps temporarily relieve light sensitivity

Maintain/support general health and wellbeing

Traditionally used in Homoeopathic medicine to decrease/reduce halitosis/bad breath

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 helps reduce occurrence of abdominal spasm

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of nervous indigestion

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

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

### Indication Requirements

Product presentation must only refer to mild migraine.



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Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
 Product presentation must only refer to mild anxiety.  
 Product presentation must not imply or refer to chronic fatigue syndrome.  
 Product presentation must only refer to mild nerve pain/neuralgia.  
 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**

Contains homeopathic ingredients.  
 If symptoms persist consult your healthcare practitioner (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 (Homeopathic)</b>	<b>5 microgram</b>
<b>dibasic potassium phosphate</b>	<b>60 mg</b>
Equivalent: potassium	26.94 mg
<b>magnesium phosphate pentahydrate</b>	<b>100 mg</b>
Equivalent: magnesium	20.66 mg
<b>magnesium phosphate pentahydrate (Homeopathic)</b>	<b>5 microgram</b>

**Other Ingredients (Excipients)**

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

Public Summary

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