



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	127005	Active Elements Active 4.1 Tablets
ARTG entry for	Medicine Listed	
Sponsor	Active Elements Pty Ltd	
Postal Address	50 Fairbairn Avenue, MOUNT MARTHA, VIC, 3934 Australia	
ARTG Start Date	18/04/2006	
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 . Active Elements Active 4.1 Tablets

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

- Traditionally used in Homoeopathic medicine to decrease/reduce ear irritation/inflammation
- Traditionally used in Homoeopathic medicine to relieve eye discomfort
- Traditionally used in Homoeopathic medicine to relieve eye redness
- Traditionally used in Homoeopathic medicine to relieve eye soreness
- 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
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild joint aches and pains
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve mild muscle spasms/twitches
- 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 helps temporarily decrease/reduce/relieve symptoms of mild vaginitis
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve bronchial mucous congestion
- Traditionally used in Homoeopathic medicine to loosen respiratory tract mucous
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild throat inflammation
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild throat infection
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation
- 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 mild eczema/dermatitis
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of facial cold sores

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild joint symptoms.



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Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must only refer to mild vaginitis.

Product presentation must not imply or refer to serious infections.

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 eczema.

Product presentation must not imply or refer to recurrent or persistent mouth lesions.

Product presentation must only refer to mild nerve pain/neuralgia.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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 mouth ulcers.

Product presentation must only refer to mild tonsillitis.

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).

If symptoms persist consult your healthcare practitioner (or words to that effect).

Contains homoeopathic ingredients.

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.

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

dibasic sodium phosphate	250 mg
Equivalent: sodium	80.97 mg
dibasic sodium phosphate dodecahydrate (Homeopathic)	5 microgram
ferrous phosphate octahydrate (Homeopathic)	5 microgram
Equivalent: iron	1.67 microgram
iron phosphate	12 mg
Equivalent: iron	4 mg
magnesium phosphate pentahydrate	100 mg
Equivalent: magnesium	20.66 mg
magnesium phosphate pentahydrate (Homeopathic)	5 microgram
potassium chloride (Homeopathic)	5 microgram
Equivalent: potassium	1.67 microgram

Other Ingredients (Excipients)

- Acacia
- calcium phosphate
- colloidal anhydrous silica
- inulin
- magnesium stearate

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microcrystalline cellulose

potassium chloride

soy polysaccharide

tapioca starch

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