



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	127311	Active Elements Active 7.1 Tablets
ARTG entry for	Medicine Listed	
Sponsor	Active Elements Pty Ltd	
Postal Address	50 Fairbairn Avenue, MOUNT MARTHA, VIC, 3934 Australia	
ARTG Start Date	26/04/2006	
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 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

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

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.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Respiratory tract infections must be qualified by 'mild'.

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

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: 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 only refer to mild tonsillitis.

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 liver disease, such as cirrhosis, hepatitis.

Product presentation must only refer to mild mouth ulcers.

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

Contains homoeopathic ingredients.

Not for the treatment of iron deficiency conditions (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 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).

If symptoms persist consult your healthcare practitioner (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.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

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