



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	127004 Active Elements Active 4.2 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 4.2 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 chronic fatigue syndrome.
Label statement: If fluid retention persists, seek medical advice (or words to that effect).
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 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 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 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 fluid retention persists, seek medical advice (or words to that effect).
Contains homoeopathic ingredients.
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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1. Formulation 1

Dosage Form	Tablet, uncoated
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Route of Administration	Oral
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Visual Identification

Active Ingredients

dibasic potassium phosphate	60 mg
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Equivalent: potassium	26.94 mg
dibasic potassium phosphate (Homeopathic)	5 microgram
magnesium phosphate pentahydrate	100 mg
Equivalent: magnesium	20.66 mg
magnesium phosphate pentahydrate (Homeopathic)	5 microgram
sodium chloride (Homeopathic)	5 microgram
sodium sulfate (Homeopathic)	5 microgram
sodium sulfate	200 mg
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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