



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	127003	Active Elements Active 4.3 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 4.3 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/relieve excessive perspiration/sweating
- Traditionally used in Homoeopathic medicine to maintain/support healthy growth and development in children
- Maintain/support general health and wellbeing
- Traditionally used in Homoeopathic medicine to maintain/support hair health
- Traditionally used in Homoeopathic medicine to decrease/reduce hair loss/thinning
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve teething/tooth pain
- Traditionally used in Homoeopathic medicine to decrease/reduce nail brittleness/splitting/chipping
- Traditionally used in Homoeopathic medicine to maintain/support nail health/strength/thickness
- 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 mild joint inflammation/swelling
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild joint stiffness
- Traditionally used in Homoeopathic medicine to maintain/support healthy blood circulation
- Traditionally used in Homoeopathic medicine to maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Maintain/support blood health
- Traditionally used in Homoeopathic medicine to relieve cold hands and feet/limbs
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild varicose veins
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle cramps
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild nerve pain/neuralgia
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild tonsillitis
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve skin dryness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve skin peeling/cracking
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of boils
- Traditionally used in Homoeopathic medicine to maintain/support skin health
- Traditionally used in Homoeopathic medicine to relieve urinary frequency



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Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.
 Product presentation must only refer to mild varicose veins.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must only refer to mild joint symptoms.
 Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 Product presentation must not imply or refer to serious conditions associated with alopecia e.g. autoimmune disease, chemotherapy.
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
 Product presentation must only refer to mild nerve pain/neuralgia.
 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).
 Not for the treatment of iron deficiency conditions (or words to that effect).
 Contains homoeopathic ingredients.

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

calcium fluoride (Homeopathic)	5 microgram
calcium phosphate	200 mg
Equivalent: calcium	77.53 mg
calcium phosphate (Homeopathic)	5 microgram
ferrous phosphate octahydrate (Homeopathic)	5 microgram
Equivalent: iron	0 mg
iron phosphate	12 mg
Equivalent: iron	4 mg
silicon dioxide (Homeopathic)	5 microgram
silicon dioxide	60 mg

Other Ingredients (Excipients)

Acacia
chlorophyllin-copper complex
inulin
magnesium stearate
microcrystalline cellulose
soy polysaccharide
tapioca starch



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