



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	127006	Active Elements Active 3.2 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 3.2 Tablets

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

Traditionally used in Homoeopathic medicine to relieve itchy ears
Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Homoeopathic medicine to relieve eye soreness
Maintain/support general health and wellbeing
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 flatulence/carminative
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal spasm
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Traditionally used in Homoeopathic medicine to relieve digestive discomfort
Traditionally used in Homoeopathic medicine to relieve digestive discomfort
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 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 morning sickness
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve bronchial mucous congestion
Traditionally used in Homoeopathic medicine to loosen chest phlegm
Traditionally used in Homoeopathic medicine to loosen respiratory tract mucous
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of dandruff
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 mild psoriasis
Traditionally used in Homoeopathic medicine to relieve urinary frequency

Indication Requirements

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



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Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to chronic fatigue syndrome.

Label statement: If symptoms persist or worsen talk to your medical practitioner.

Product presentation must only refer to mild joint symptoms.

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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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.

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 nerve pain/neuralgia.

Product presentation must not imply or refer to severe morning sickness such as hyperemesis gravidarum

Product presentation must only refer to mild psoriasis

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

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).

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Contains homoeopathic ingredients.

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

If coughing persists consult your doctor (or a healthcare professional) (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
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
magnesium phosphate pentahydrate (Homeopathic)	5 microgram
magnesium phosphate pentahydrate	100 mg
Equivalent: magnesium	20.66 mg
potassium sulfate	60 mg
Equivalent: potassium	26.92 mg
potassium sulfate (Homeopathic)	5 microgram

Other Ingredients (Excipients)

Acacia

calcium phosphate

colloidal anhydrous silica

inulin

magnesium stearate

microcrystalline cellulose

soy polysaccharide

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tapioca starch

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