

# **Australian Government**

### **Department of Health**

## Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: Active Elements Active 2.1 Tablets 126980

ARTG entry for Medicine Listed

Sponsor Active Elements Pty Ltd

Postal Address 50 Fairbairn Avenue, MOUNT MARTHA, VIC, 3934

13/04/2006 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

#### 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 2.1 Tablets

**Product Type** Effective Date 4/03/2021 Single Medicine Product

## **Permitted Indications**

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve excessive perspiration/sweating

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 nail brittleness/splitting/chipping

Traditionally used in Homoeopathic medicine to maintain/support nail health/strength/thickness

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 decrease/reduce/relieve symptoms of mild varicose veins

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

### **Indication Requirements**

Product presentation must only refer to mild joint symptoms.

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

Product presentation must only refer to mild varicose veins.

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.

#### Standard Indications

No Standard Indications included on Record

#### **Specific Indications**

No Specific Indications included on Record

### Warnings

#### Page 1 of 2

#### Produced at 31.08.2021 at 06:13:26 AEST This is not an ARTG Certificate document.



# **Australian Government**

### **Department of Health**

### Therapeutic Goods Administration

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

Contains homoeopathic ingredients.

#### **Additional Product information**

Pack	Size/	Poison	inf	formation

Pack Size Poison Schedule

#### Components

### 1 . Formulation 1

Dosage Form Tablet, uncoated

Route of Administration Or

Visual Identification

**Active Ingredients** 

calcium fluoride (Homeopathic) 5 microgram silicon dioxide (Homeopathic) 5 microgram silicon dioxide 60 mg

written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.

Other Ingredients (Excipients)

Acacia

calcium phosphate

chlorophyllin-copper complex

inulin

magnesium stearate microcrystalline cellulose

soy polysaccharide tapioca starch

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior