Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 376615 Kids' Astragalus 8 Immune Shield

ARTG entry for Medicine Listed

 Sponsor
 McPherson's Consumer Products Pty Ltd

 Postal Address
 Locked Bag 5018, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 20/10/2021

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 . Kids' Astragalus 8 Immune Shield

Product Type Single Medicine Product Effective Date 20/10/2021

Permitted Indications

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood

Traditionally used in Chinese medicine to stabilise Exterior

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi

Traditionally used in Chinese medicine to support protective qi

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify/invigorate spleen

Traditionally used in Chinese medicine to release exterior/exogenous wind-coldness

Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-heat

Traditionally used in Chinese medicine to helps enhance/promote/increase vitality

Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating

Traditionally used in Chinese medicine to maintain/support general health and wellbeing

Traditionally used in Chinese medicine to decrease/reduce/relieve loss of appetite

Maintain/support healthy appetite

Maintain/support immune system health

Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity

Maintain/support healthy immune system function

Helps reduce occurrence of common colds

Traditionally used in Chinese medicine to helps reduce occurrence of common colds

Traditionally used in Chinese medicine to helps reduce occurrence of common colds

Indication Requirements

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

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

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to disease in any body organ.

Product presentation must not imply or refer to eating disorders.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormOral LiquidRoute of AdministrationOral

Visual Identification

Active Ingredients

Astragalus membranaceus root Extract dry concentrate 20.54 mg/mL Equivalent: Astragalus membranaceus (Dry) 308.1 mg/mL Atractylodes macrocephala root Extract dry concentrate 20.54 mg/mL Equivalent: Atractylodes macrocephala (Dry) 102.7 mg/mL Sambucus nigra fruit Juice concentrate 17.921 mg/mL Equivalent: Sambucus nigra (Fresh) 215.05 mg/mL Saposhnikovia divaricata root Extract dry concentrate 20.54 mg/mL Equivalent: Saposhnikovia divaricata (Dry) 102.7 mg/mL 2.16 mg/mL zinc gluconate Equivalent: zinc .28 mg/mL

Other Ingredients (Excipients)

citric acid

d-alpha-tocopheryl acetate

Flavour glycerol

maltodextrin

potassium sorbate

purified water

Stevia rebaudiana

xanthan gum

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