



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 120483 | Schuessler Tissue Salts Painful Teeth Comb R |
| ARTG entry for | Medicine Listed (Export Only) | |
| Sponsor | Martin & Pleasance Pty Ltd | |
| Postal Address | PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia | |
| ARTG Start Date | 12/07/2005 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Export only Medicines | |

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . Schuessler Tissue Salts Painful Teeth Comb R

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|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 12/07/2005 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Schuessler Tissue Salts Painful Teeth Comb R is a homoeopathic preparation that has been used for the temporary relief of teething, tooth pain and dental inflammation.

Warnings

- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Homoeopathic product without approved therapeutic indications (or words to that effect).
- Homoeopathic product/preparation or medicine (or words to that effect)
- Contains lactose (or words to that effect).
- (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

- 1 . Medicine Component

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Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--|---------|
| calcium fluoride (Homeopathic) | 4.85 mg |
| calcium hydrogen phosphate dihydrate (Homeopathic) | 4.85 mg |
| ferric pyrophosphate (Homeopathic) | 4.85 mg |
| magnesium phosphate pentahydrate (Homeopathic) | 4.85 mg |
| silicon dioxide (Homeopathic) | 4.85 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
lactose monohydrate
magnesium stearate

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