



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	176769	Calcimax Plus Capsules
<b>ARTG entry for</b>	Medicine Listed (Export Only)	
<b>Sponsor</b>	Ozmed Health International	
<b>Postal Address</b>	36 Upper Wilsons Road, BARDWELL VALLEY, NSW, 2207 Australia	
<b>ARTG Start Date</b>	19/10/2010	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

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 therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

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 . Calcimax Plus Capsules

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/10/2010
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#### Permitted Indications

No Permitted Indications included on Record

#### Indication Requirements

No Indication Requirements included on Record

#### Standard Indications

Source of calcium. May assist in the prevention and/or treatment of osteoporosis.

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, soft

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

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calcium carbonate	875 mg
colecalfiferol	200 IU

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
Gelatin  
glycerol  
hydrogenated vegetable oil  
lecithin  
purified water  
Soya Oil  
titanium dioxide  
vanillin  
yellow beeswax

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