



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

## Public Summary

<b>Summary for ARTG Entry:</b>	211676	Calcium Excel
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	McPherson's Consumer Products Pty Ltd	
<b>Postal Address</b>	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
<b>ARTG Start Date</b>	2/07/2013	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Calcium Excel

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/06/2020
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### Permitted Indications

Aids/assists teeth development

Maintain/support healthy teeth

Maintain/support teeth strength

Maintain/support healthy body tissues

Maintain/support bone health in adolescents

Maintain/support bone health

Maintain/support bone health in children

Aids/assists healthy bone development/growth/building in adolescents

Aids/assists healthy bone development/growth/building in children

Maintain/support bone mass/density/integrity

Maintain/support (state mineral) absorption in bones

Maintain/support bone strength

Maintain/support bone strength in children

Maintain/support bone strength in adolescents

Help maintain/support bone mineralisation

A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate in post-menopausal women

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life in post-menopausal women

Maintain/support healthy immune system function

Maintain/support healthy muscle contraction function

Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate

Maintain/support (state vitamin/mineral/nutrient) levels in the body



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**Indication Requirements**

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Indication can only be used for medicines that contain calcium as an active ingredient and the recommended daily dose of the medicine must provide at least 290 milligrams of elemental calcium.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**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**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>calcium citrate tetrahydrate</b>	<b>721.5 mg</b>
Equivalent: calcium	150 mg
<b>calcium glycinate</b>	<b>676.41 mg</b>
Equivalent: calcium	150 mg
<b>colecalfiferol</b>	<b>.0125 mg</b>

**Other Ingredients (Excipients)**

- Carnauba Wax**
- colloidal anhydrous silica**
- dl-alpha-tocopherol**
- hydrogenated soya oil**
- hydrolysed gelatin**
- hypromellose**
- macrogol 400**
- magnesium stearate**
- maize starch**
- maltodextrin**
- microcrystalline cellulose**
- silicon dioxide**
- sucrose**



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