



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	405886	MOMCAL
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Contract Manufacturing & Packaging Services Pty Ltd	
<b>Postal Address</b>	20-24 Long Street, Smithfield, NSW, 2164 Australia	
<b>ARTG Start Date</b>	7/03/2023	
<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.

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 . MOMCAL

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/03/2023
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#### Permitted Indications

- Maintain/support general health and wellbeing in elderly individuals
- Maintain/support general health and wellbeing in post-partum women
- Maintain/support general health and wellbeing in breastfeeding women
- Maintain/support general health and wellbeing
- Maintain/support bone health in post-menopausal women
- Maintain/support bone health
- Maintain/support bone mass/density/integrity in post-menopausal women
- Maintain/support bone strength
- Maintain/support bone strength in post-menopausal women
- Help maintain/support bone mineralisation
- Help maintain/support bone mineralisation in post-menopausal women
- A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate
- 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
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy cardiovascular system function in elderly individuals
- Maintain/support healthy digestive system function in elderly individuals
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy muscle contraction function in elderly individuals
- Maintain/support muscle function
- Maintain/support muscle function in elderly individuals
- Maintain/support healthy neuromuscular system/function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate in post-partum women
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in post-partum women

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- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate in breastfeeding women
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in post-partum women
- Maintain/support nerve conduction in elderly individuals
- Maintain/support neuromuscular function in elderly individuals
- Maintain/support nervous system function in elderly individuals
- Enhance/promote healthy foetal development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Helps enhance/promote maternal health
- Maintain/support maternal health

**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.

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).

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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).

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

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.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

**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**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule

**Components**

1 . Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral

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**Visual Identification**

**Active Ingredients**

<b>calcium carbonate</b>	<b>625 mg</b>
Equivalent: calcium	250 mg
<b>colecalfiferol</b>	<b>10 microgram</b>
Equivalent: colecalfiferol	400 IU

**Other Ingredients (Excipients)**

- allura red AC
- Gelatin
- glycerol
- hydrogenated coconut oil
- lecithin
- purified water
- Soya Oil
- titanium dioxide
- yellow beeswax

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