



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

## Public Summary

<b>Summary for ARTG Entry:</b>	319297	REPAREN
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Interclinical Laboratories Pty Ltd	
<b>Postal Address</b>	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	26/06/2019	
<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 . REPAREN

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	12/04/2021
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#### Permitted Indications

- Maintain/support energy production in children
- Maintain/support energy production
- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support healthy growth and development in children
- Maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing
- Aids/assists teeth development in children
- Maintain/support healthy teeth
- Maintain/support healthy teeth in children
- Maintain/support healthy body tissues
- Maintain/support bone health
- Maintain/support bone health in children
- Aids/assists healthy bone development/growth/building in children
- Maintain/support bone mass/density/integrity
- Maintain/support bone strength
- Maintain/support bone strength in children
- A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate
- Helps maintain/support joint cartilage health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support healthy digestive system function
- Maintain/support healthy digestive system function in children
- Maintain/support healthy muscle contraction function in children
- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support muscle function in children
- Aid/assist/helps protein synthesis in the body

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Aid/assist/helps protein synthesis in the body in children  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children  
Maintain/support nerve conduction in children  
Maintain/support nerve conduction  
Maintain/support neuromuscular function in children  
Maintain/support neuromuscular function  
Maintain/support nervous system function  
Maintain/support nervous system function in children  
Maintains/support healthy foetal development  
Maintain/support maternal health

**Indication Requirements**

Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.  
Product presentation must not imply or refer to serious cardiovascular conditions.  
If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.  
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: If you are concerned about the health of yourself or your baby, talk to your health practitioner.  
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.  
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.  
If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

**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**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>monobasic calcium phosphate</b>	<b>750 mg</b>
Equivalent: calcium	128.4 mg
Equivalent: phosphorus	198.525 mg

**Other Ingredients (Excipients)**

hypromellose  
magnesium stearate

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