



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	319297	REPAREN
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	26/06/2019	
Product Category	Medicine	
Status	Active	
Approval Area	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

Product Type	Single Medicine Product	Effective Date	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 in children
Maintain/support healthy teeth
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 in children
Maintain/support bone strength
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 in children

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Aid/assist/helps protein synthesis in the body
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 in children
Maintain/support nervous system function
Maintains/support healthy foetal development
Maintain/support maternal health

Indication Requirements

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.

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

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

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

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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).

If directed to women, 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.

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

monobasic calcium phosphate	750 mg
Equivalent: calcium	128.4 mg
Equivalent: phosphorus	198.525 mg

Other Ingredients (Excipients)

hypromellose
magnesium stearate

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