



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	328981	AdvaCal Forte
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	21/01/2020	
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 . AdvaCal Forte

Product Type	Single Medicine Product	Effective Date	6/11/2020
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Permitted Indications

Maintain/support energy levels
Aids/assists teeth development
Maintain/support healthy teeth
Maintain/support teeth mineralisation
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Aids/assists healthy bone development/growth/building in aging individuals
Maintain/support bone strength in aging individuals
Maintain/support bone strength
Help maintain/support bone mineralisation in aging individuals
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
Maintain/support healthy cardiovascular system function
Maintain/support artery health
Maintain/support healthy immune system function
Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate
Maintain/support healthy muscle contraction function
Maintain/support muscle function
Maintain/support muscle relaxation
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support nervous system function

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



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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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

Product presentation must not imply or refer to chronic fatigue syndrome.

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

Label statement: If symptoms persist, talk to your health professional.

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 cardiovascular conditions.

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).

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
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

borax	8.82 mg
Equivalent: boron	1 mg
calcium citrate tetrahydrate	792.22 mg
Equivalent: calcium	167 mg
colecalfiferol	.0083 mg
colloidal anhydrous silica	15.53 mg
Equivalent: silicon	7.26 mg
copper gluconate	1.43 mg
Equivalent: copper	200 microgram
heavy magnesium oxide	96.19 mg
Equivalent: magnesium	58 mg
hydroxyapatite	759.09 mg
Equivalent: phosphorus	68.32 mg
Equivalent: calcium	167 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	1 mg
menaquinone 7	30 microgram
zinc amino acid chelate	16 mg
Equivalent: zinc	3.2 mg

Other Ingredients (Excipients)

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Acacia
citric acid
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
glycine
lecithin
macrogol 3000
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
polyvinyl alcohol
povidone
purified talc
silicon dioxide
sucrose
titanium dioxide

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