



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374335	Nalgestic Forte
ARTG entry for	Medicine Listed	
Sponsor	Nutrition Care Pharmaceuticals Pty Ltd	
Postal Address	25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia	
ARTG Start Date	7/09/2021	
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 . Nalgestic Forte

Product Type	Single Medicine Product	Effective Date	7/09/2021
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Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support bone health
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- 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
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in elderly individuals

Indication Requirements

- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- 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.
- 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).
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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

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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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

colecalfiferol	5 microgram
Equivalent: colecalfiferol	200 IU
curcumin	12.7554 mg

Other Ingredients (Excipients)

- ascorbic acid
- betadex
- calcium carbonate
- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- crospovidone
- iron oxide red
- iron oxide yellow
- macrogol 3350
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- polyvinyl alcohol
- purified talc
- titanium dioxide

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