



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	348470	Osteoblast
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Limited	
Postal Address	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
ARTG Start Date	14/11/2020	
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 . Osteoblast

Product Type	Single Medicine Product	Effective Date	14/11/2020
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Maintain/support collagen formation
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support teeth strength
- Maintain/support connective tissue health
- Helps enhance/promote bone health
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone mass/density/integrity
- Maintain/support (state mineral) absorption in bones
- Maintain/support bone healing/repair
- Maintain/support bone strength
- Helps enhance/promote bone mineralisation
- 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
- 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 muscle health
- Maintain/support muscle function
- Maintain/support muscle strength
- Maintain/support (state vitamin/mineral/nutrient) levels in the body

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).

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is



Australian Government
Department of Health
 Therapeutic Goods Administration

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.

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.

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

borax	8.82 mg
Equivalent: boron	1 mg
calcium carbonate	1.125 g
Equivalent: calcium	450 mg
colecalfiferol	.0125 mg
copper gluconate	5.72 mg
Equivalent: copper	800 microgram
heavy magnesium oxide	190 mg
Equivalent: magnesium	114.61 mg
hydroxyapatite	217.39 mg
Equivalent: calcium	50 mg
manganese gluconate	21.93 mg
Equivalent: manganese	2.5 mg
menaquinone 7	45 microgram
phytomenadione	23 microgram
silicon dioxide	15.52 mg
Equivalent: silicon	7.25 mg
zinc oxide	6.22 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

- Acacia
- Carnauba Wax
- croscarmellose sodium
- dl-alpha-tocopherol
- hydrogenated soya oil
- hydrolysed gelatin
- lecithin
- macrogol 3000
- magnesium stearate

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

maize starch
maltodextrin
microcrystalline cellulose
polyvinyl alcohol
povidone
purified talc
purified water
silicon dioxide
sucrose
titanium dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary