# 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.

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.

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 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.

**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 |
| **colecalciferol** | **.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**

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



Public Summary