PROFESSIONAL INFORMATION
NATIVA COMPLEX® CalMag tablets
- Complementary Medicine.
- D.34.12 Health Supplements – Multiple substance formulation.
- Health Supplements are intended only to complement health or supplement the diet. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
NATIVA COMPLEX® CalMag (tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

Active ingredients	Per tablet	Per maximum daily dose (2 tablets)	% NRV# per maximum daily dose
Calcium carbonate Dicalcium phosphate providing total Calcium (elemental)	1028,71 mg 300 mg 500 mg	2057,42 mg 600 mg 1000 mg	77 % *
Inulin	250 mg	500 mg	48 %
Magnesium oxide providing Magnesium (elemental)	166,67 mg 100 mg	333,34 mg 200 mg	136 %
Zinc AAC** providing Zinc (elemental)	75 mg 7,5 mg	150 mg 15 mg	157 %
Manganese sulphate providing Manganese (elemental)	5,62 mg 1,8 mg	11,24 mg 3,6 mg	111 %
Copper AAC** providing Copper (elemental)	5 mg 0,5 mg	10 mg 1 mg	40 %
Cholecalciferol (Vitamin D3)	240 IU (6 µg)	480 IU (12 µg)	

Nutrient reference values for adults and children older than 4 years.
* NRV not established.
**Amino Acid Chelate.
Nativa Complex® CalMag is sugar free.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablet.
Nativa Complex® CalMag tablets are oblong shaped, white and film-coated.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Nativa Complex® CalMag is a calcium-magnesium supplement that contains 500 mg calcium with prebiotics, vitamin D3 and magnesium for better absorption, as well as added minerals for better utilisation. The 500 mg of calcium per dosage is the highest quantity that can be absorbed in one dosage. Nativa Complex® CalMag also contains added minerals such as copper, manganese and zinc to help bone mineralisation. Nativa Complex® CalMag can assist the body to build and maintain healthy bones and teeth. Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis and can help to prevent osteoporosis.
Efficacy of support may vary between users.
4.2 Posology and method of administration
The recommended daily dosage is
Adults:
One (1) tablet in the morning and one (1) tablet in the evening, after a meal, with a glass of water.
Advise the patient to not take dosage at the same time as other medications (see **4.5**).
Children:
This product should only be used in children under the guidance of a relevant healthcare practitioner. Dosage can be adjusted based on the nutritional requirements of the specific age group.
4.3 Contraindications
- Must not be given to patients with known hypersensitivity to any of the ingredients of Nativa Complex® CalMag (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- Patients taking any chronic medication should not use this product without consulting their medical practitioner.

4.4 Special warnings and precautions for use
- Patients with a liver disorder should consult a doctor before use as Nativa Complex® CalMag contains manganese.
- Patients with bleeding disorders or taking anticoagulants/blood thinners or anti-platelet medication should use this product with caution (see **4.5**).
- Patients with the rare hereditary condition of sorbitol intolerance should not take Nativa Complex® CalMag.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.

Porphyria
Safety has not been established.
4.5 Interaction with other medicinal products and other forms of interactions
No interaction studies have been performed on Nativa Complex® CalMag, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Magnesium	Blood thinners (anticoagulant or anti-platelet medication) e.g. warfarin	May have a blood thinning effect increasing the risk of bleeding.
Minerals (magnesium, zinc, iron, calcium)	Antibiotics	The absorption of antibiotics may be decreased. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements.
Calcium, magnesium	Bisphosphonates	May reduces the absorption of bisphosphonates, should be taken at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements.
Calcium	Intergrase inhibitors e.g. dolutegravir, elvitegravir and raltegravir	May reduce levels, should be taken at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements.
Calcium	Beta blockers e.g. sotalol (Betapace)	May reduce levels, should be taken at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements.
Calcium, magnesium	Thiazide diuretics or potassium-sparing diuretics	May increase the risk of hypercalcemia and renal failure or decrease excretion of magnesium, possibly increasing magnesium levels.
Magnesium	Levadopa/carbidopa e.g. Sinemet	May reduce the bioavailability of levodopa/carbidopa.
Calcium, magnesium	Anti-diabetic medication e.g. sulfonylureas	May increase the systemic absorption of sulfonylureas, increasing their effects and side effects.
Calcium	Vitamin D or calcium supplements	May increase the level of calcium in blood.

4.6 Fertility, pregnancy and lactation
Pregnancy
Patients who are pregnant should consult their medical practitioner for advice before using Nativa Complex® CalMag.
Breastfeeding
Patients who are breastfeeding should consult their medical practitioner for advice before using Nativa Complex® CalMag.
Fertility
There are no known effects of Nativa Complex® CalMag on fertility.
4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Nativa Complex® CalMag should not affect your ability to drive or operate machinery.
4.8 Undesirable effects
Nativa Complex® CalMag tablets are generally well tolerated with the occurrence of adverse events unknown.
Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.
Adverse reactions reported in the literature are listed below, by system organ class and frequency. Frequencies are defined as:
- very common (≥1/10)
- common (≥1/100 to <1/10)
- uncommon (≥1/1,000 to <1/100)
- rare (≥1/10,000 to 1</1,000)
- very rare (<1/10,000)

System Organ Class	Frequency	Adverse Event
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria and itching.
Gastrointestinal Disorders	Not known	Abdominal cramps, constipation, diarrhoea, nausea, vomiting, belching and flatulence.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (skin rash and itching).

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.
Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**," found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf
4.9 Overdose
Symptoms
See **4.8 Undesirable effects**
In overdose, side effects can be precipitated and/or be increased.
There is no evidence that this product can lead to an overdose when used as recommended.
Vitamin D intoxication can occur when vitamin D supplements are taken orally in excessive doses.
Due allowance should always be made for intake of these vitamins from other sources.
Treatment
If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D.34.12 Health Supplements – Multiple substance formulation
Pharmacotherapeutic classification: Vitamins and other combinations
ATC code: A11JC
Inulin
Inulin is an oligosaccharide which is composed of approximately 60 chains of glucose and fructose molecules.
Inulin is a prebiotic promoting the growth of specific types of bacteria in the large intestine.
Vitamins and minerals
A sufficient intake of vitamins and minerals is necessary to maintain normal energy metabolism, and physiological function. Unbalanced diet and insufficient dietary intake of vitamins and minerals can result in subnormal health.
5.2 Pharmacokinetic properties
Inulin
Absorption: Inulin is not digested or absorbed. Instead it promotes the growth of specific types of bacteria in the large intestine. These bacteria produce short-chain fatty acids that are absorbed and metabolized.
Vitamins and minerals
The combination of vitamins and minerals is typical of a normal diet. Therefore, the pharmacological metabolism and fate of Nativa Complex® CalMag is anticipated to be similar.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Dicalcium phosphate
Microcrystalline cellulose
Magnesium stearate
Sorbitol
Copovidone
Stearic acid
Sodium starch glycolate
6.2 Incompatibilities
None known
6.3 Shelf life
24 months
6.4 Special precautions for storage
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Do not use after the expiry date printed on the carton.

6.5 Nature and contents of container
Nativa Complex® CalMag are white, oblong shaped and film-coated tablets.
Nativa Complex® CalMag is available in a white high density polyethylene plastic container with a brown flip-top cap. It contains 60 tablets and includes a patient information leaflet in a printed unit carton.
6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Nativa (Pty) Ltd
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Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za

8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated

10. DATE OF REVISION OF THE TEXT
October 2022

PPIL144/02