

®
PATIENT INFORMATION LEAFLET

Scheduling status:
S0

NATIVA COMPLEX® CALMAG tablet

Calcium carbonate and Dicalcium phosphate (Calcium); Inulin; Magnesium oxide (Magnesium); Zinc amino acid chelate (Zinc); Manganese sulfate (Manganese); Copper amino acid chelate (Copper); Cholecalciferol (Vitamin D3).

Sugar free

- D.34.12 Complementary Medicine: 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.

Read all of this leaflet carefully because it contains important information for you.

Nativa Complex® CalMag is available without a doctor's prescription. Nevertheless, you still need to use Nativa Complex® CalMag carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Nativa Complex® CalMag with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET

1. What Nativa Complex® CalMag is and what it is used for
2. What you need to know before you take Nativa Complex® CalMag
3. How to take Nativa Complex® CalMag
4. Possible side effects
5. How to store Nativa Complex® CalMag
6. Contents of the pack and other information

1. What Nativa Complex® CalMag is and what it is used for

Nativa Complex® CalMag is 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.

2. What you need to know before you take Nativa Complex® CalMag

Do not take Nativa Complex® CalMag:

- If you are hypersensitive (allergic) to any of the ingredients of Nativa Complex® CalMag (listed in section 6 **Contents of pack and other information**).
- If you are taking any chronic medication do not use Nativa Complex® CalMag without consulting your medical practitioner.

Warnings and precautions

- Consult a healthcare provider before use if you have bleeding disorders.
- Consult a healthcare provider before use if you have a liver disorder as Nativa Complex® CalMag contains manganese.
- Do not exceed the daily recommended dose.
- If you have been told that you have an intolerance to some sugars, you should not take Nativa Complex® CalMag as it contains sorbitol.
- Do not use after the date of expiry.

Porphyria: Safety has not been established.

Tell your doctor if you are not sure about any of the above.

Other medicines and Nativa Complex® CalMag

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.) Consult your doctor, pharmacist or healthcare provider before use if you are taking:

- Blood thinners (anticoagulant - or antiplatelet medication) e.g. Warfarin, as some of the ingredients may have a blood thinning effect increasing the risk of bleeding;
- antibiotics (used to treat infections), as the minerals in Nativa Complex® CalMag may reduce their absorption. You should take all oral antibiotics at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements;
- Bisphosphonates, as the minerals in Nativa Complex® CalMag may reduce the absorption. You should take bisphosphonates at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements;
- Intergate inhibitors e.g. Dolutegravir, Elvitegravir and Raltegravir as the minerals in Nativa Complex® CalMag may reduce their absorption. You should take these medications at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements;
- Beta blockers e.g. Sotalol (Betapace) as the minerals in Nativa Complex® CalMag may reduce the absorption. You should take Beta blockers at least two (2) hours before, or four (4) hours after Nativa Complex® CalMag or similar supplements;
- Thiazide diuretics or Potassium-sparing diuretics as the minerals in Nativa Complex® CalMag may increase the risk of hypercalcemia and renal failure or decrease excretion of magnesium, possibly increasing magnesium levels;
- Levodopa/Carbidopa (Sinemet) as the minerals in Nativa Complex® CalMag may reduce the bioavailability;
- Anti-diabetic medication e.g. Sulfonylureas as the minerals in Nativa Complex® CalMag may increase the systemic absorption of sulfonylureas, increasing their effects and side effects; or
- Vitamin D or calcium supplements while taking Nativa Complex® CalMag as this may increase the level of calcium in your blood.

Take Nativa Complex® CalMag a few hours before or after other medication (see **How to take Nativa Complex® CalMag**).

Taking Nativa Complex® CalMag with food and drink

You should take Nativa Complex® CalMag after a meal with a glass of water. There is no known interaction between contents of Nativa Complex® CalMag and food and drink.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your medical practitioner for advice before using Nativa Complex® CalMag.

Driving and using machinery

Nativa Complex® CalMag should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

3. How to take Nativa Complex® CalMag

Do not share medicines with any other person.

Always take Nativa Complex® CalMag exactly as described in this leaflet or as your healthcare provider has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose for adults 18 years and older is:

One (1) tablet in the morning and one (1) tablet in the evening, with a glass of water, after a meal.

Take a few hours before or after taking other medications (see **Other medicines with Nativa Complex® CalMag**).

Children:

Use in children under the guidance of a relevant healthcare practitioner. Dosage can be adjusted based on the nutritional requirements of the specific age group

If you take more Nativa Complex® CalMag than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

If you forget to take Nativa Complex® CalMag

Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Nativa Complex® CalMag

If you are taking the dose as indicated, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

Nativa Complex® CalMag can have side effects.

Not all side effects reported for Nativa Complex® CalMag are included in this leaflet. Should your general health worsen while taking this medicine, or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

If any of the following or other side effects occur, stop taking this product and consult your doctor or pharmacist or go to the casualty department at your nearest hospital:

Allergic reactions such as: skin rashes, hives (skin bumps), itchiness, swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing.

Tell your doctor or pharmacist if you notice any of the following:

Frequency unknown:

- Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria (hives), skin rash and itching.
- Abdominal cramps, constipation, diarrhoea, nausea, vomiting, belching and flatulence.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications:

https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf.

By reporting side effects, you can help provide more information on the safety of Nativa Complex® CalMag.

5. How to store Nativa Complex® CalMag

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store in a dry place at or below 25 °C.
- Protect from light.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What Nativa Complex® CalMag contains

Active Ingredients	Per tablet	Per maximum daily dose (2 tablets)	% NRV* per 2 tablets (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	*
Magnesium oxide providing Magnesium (elemental)	166,67 mg 100 mg	333,34 mg 200 mg	48 %
Zinc AAC** providing Zinc (elemental)	75 mg 7,5 mg	150 mg 15 mg	136 %
Manganese sulphate providing Manganese (elemental)	5,62 mg 1,8 mg	11,24 mg 3,6 mg	157 %
Copper AAC** providing Copper (elemental)	5 mg 0,5 mg	10 mg 1 mg	111 %
Cholecalciferol (Vitamin D3)	240 IU (6 µg)	480 IU (12 µg)	40 %

* Nutrient reference values for adults and children older than 4 years.

* NRV not established.

**Amino Acid Chelate.

The other ingredients or excipients are: Dicalcium phosphate, microcrystalline cellulose, magnesium stearate, sorbitol, copovidone, stearic acid and sodium starch glycolate.

Nativa Complex® CalMag is sugar free.

What Nativa Complex® CalMag looks like and contents of the pack

Nativa Complex® CalMag are oblong shaped, white and film-coated tablets, available in a white plastic container with a brown flip-top cap. It contains 60 tablets and includes a patient information leaflet in a printed unit carton.

Holder of Certificate of Registration

Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa

Tel: +27 (0) 12 664 7110

Customer care line: 0860 628 482

Email: health@nativa.co.za

Website: www.nativa.co.za

This leaflet was last revised in

July 2022

Date of registration

To be allocated

Registration number

To be allocated

Professional Information

The Nativa Complex® CalMag Professional Information may be obtained from the Nativa website (www.nativa.co.za).