

PATIENT INFORMATION LEAFLET

Scheduling status:

S0

NATIVA COMPLEX® ZINC PLUS capsule

Ascorbic acid (Vitamin C); Zinc amino acid chelate (Zinc); DL-alpha-tocopheryl acetate (Vitamin E); Copper amino acid chelate (Copper); Retinyl palmitate (Vitamin A).

Sugar free

- 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.

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

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

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

WHAT IS IN THIS LEAFLET

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

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

Nativa Complex® Zinc Plus is a health supplement indicated for the support of the immune system, helping to prevent infections. Nativa Complex® Zinc Plus is specially formulated for the maintenance of a healthy body and skin and to provide antioxidant protection.

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

Do not take Nativa Complex® Zinc Plus:

- If you are hypersensitive (allergic) to any of the ingredients of Nativa Complex® Zinc Plus (see section 6).
- If you have high levels of vitamin A in your body as Nativa Complex® Zinc Plus contains vitamin A. Excessive amounts of vitamin A can cause hypervitaminosis A.

Warnings and precautions

Ask your doctor if you are not sure about any of the below.

- If you have a history of oxalate kidney stones avoid high doses of vitamin C due to increased risk of kidney stone formation.

Porphyria: Safety has not been established.

Other medicines with Nativa Complex® Zinc Plus

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:

- Patients who are taking retinoids should avoid using Nativa Complex® Zinc Plus as it contains vitamin A and may have an additive toxic effect.
- Blood thinners as Nativa Complex® Zinc Plus contains vitamin E which may increase the risk of bleeding.
- Antibiotics (used to treat infections), as the magnesium, zinc and iron in Nativa Complex® Zinc Plus may reduce their absorption. You should take all oral antibiotics at least two (2) hours before, or four (4) hours after Nativa Complex® Zinc Plus or similar supplements.

Taking Nativa Complex® Zinc Plus with food and drink

You should take Nativa Complex® Zinc Plus after breakfast, with a glass of water. There is no known interaction between contents of Nativa Complex® Zinc Plus and food and drink.

Pregnancy and Breastfeeding

- Do not use Nativa Complex® Zinc Plus if you are pregnant or breastfeeding as safety has not been established.

Driving and using machinery

Nativa Complex® Zinc Plus should not affect your ability to drive or operate 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® Zinc Plus

Do not share medicines with any other person.

Always take Nativa Complex® Zinc Plus 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 is:

Take two (2) capsules per day, after a meal, with a glass of water.

Children 12 years and older:

Take one (1) capsule per day, after a meal, with a glass of water.

If you take more Nativa Complex® Zinc Plus 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® Zinc Plus

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® Zinc Plus

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® Zinc Plus can have side effects.

Not all side effects reported for Nativa Complex® Zinc Plus are included in this leaflet.

Should your general health worsen while taking this medicine, or if you experience any undesired effects while taking Nativa Complex® Zinc Plus, please consult your healthcare practitioner for advice.

Like all medicines, this medicine can cause side effects although not everybody gets them.

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:

- Abdominal discomfort, constipation, decreased appetite, diarrhea, difficulty swallowing (dysphagia), gas (flatulence), heartburn, nausea, vomiting.

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® Zinc Plus.

5. How to store Nativa Complex® Zinc Plus

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store in a dry place at or below 25 °C.
- Keep the container tightly closed.
- 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® Zinc Plus contains

Active ingredient	Per capsule	Per max daily dose (2 capsules)	%NRV* per 2 capsules (max daily dosage)
Ascorbic acid (Vitamin C)	50 mg	100 mg	100%
Zinc AAC* Providing Zinc (elemental)	125 mg 12,5 mg	250 mg 25 mg	227 %
DL-alpha-tocopheryl acetate (Vitamin E)	4,4 IU (2,96 mg a-TE**)	8,8 IU (5,92 mg a-TE**)	40 %
Copper AAC* Providing Copper (elemental)	6,8 mg 0.68 mg	13,6 mg 1,36 mg	151 %
Retinyl palmitate (Vitamin A)	1000 IU (300 µg RAE***)	2000 IU (600 µg RAE***)	67%

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

*Amino Acid Chelate.

**D-alpha-Tocopherol Equivalents.

***Retinol Activity Equivalents.

The other ingredients or excipients are: gelatine capsule (capsule constituents: bovine gelatine, allura red, quinolone yellow, brilliant blue, titanium dioxide), maize starch, microcrystalline cellulose, magnesium stearate.

Nativa Complex® Zinc Plus is sugar free.

What Nativa Complex® Zinc Plus looks like and contents of the pack

Nativa Complex® Zinc Plus are white and blue capsules, available in a white plastic container with turquoise flip-top cap. It contains 60 capsules and includes a patient information leaflet in a printed unit carton.

Holder of Certificate of Registration

Nativa (Pty) Ltd

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This leaflet was last revised in

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

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