

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

NATIVA COMPLEX® Multi-Defence capsule

Ascorbic acid (Vitamin C), Calcium ascorbate (Vitamin C and Calcium), Cholecalciferol (Vitamin D3), Selenium glycinate (Selenium and Glycine), Zinc glycinate (Zinc and Glycine).

Sugar and preservative free.

- Complementary Medicine: D.34.12 Health Supplements – Multiple substance formulation.
- A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. 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® Multi-Defence is available without a doctor's prescription. Nevertheless, you still need to use Nativa Complex® Multi-Defence carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Do not share Nativa Complex® Multi-Defence 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® Multi-Defence is and what it is used for
2. What you need to know before you take Nativa Complex® Multi-Defence
3. How to take Nativa Complex® Multi-Defence
4. Possible side effects
5. How to store Nativa Complex® Multi-Defence
6. Contents of the pack and other information

1. What Nativa Complex® Multi-Defence is and what it is used for

Nativa Complex® Multi-Defence is a health supplement indicated for the maintenance of the immune system and to provide antioxidant support. Nativa Complex® Multi-Defence supports the development and maintenance of bones, cartilage, teeth and gums. Nativa Complex® Multi-Defence includes easily absorbable nutrients.

2. What you need to know before you take Nativa Complex® Multi-Defence

Do not take Nativa Complex® Multi-Defence:

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

Warnings and precautions

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

- Consult a healthcare provider prior to use if you have a history of non-melanoma skin cancer as Nativa Complex® Multi-Defence contains selenium.
- Consult a healthcare provider prior to use if you have a history of kidney stones as Nativa Complex® Multi-Defence contains vitamin C and vitamin D.
- Consult a healthcare provider prior to use if you have high levels of calcium in your blood (hypercalcaemia) or in your urine (hypercalciuria) as Nativa Complex® Multi-Defence contains vitamin D, which can worsen the conditions.
- Consult a healthcare provider prior to use if you have high levels of phosphate in your blood (hyperphosphataemia) as Nativa Complex® Multi-Defence contains vitamin D, which can worsen hyperphosphataemia.
- Do not exceed the daily recommended dose.
- 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® Multi-Defence

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicines.

Consult your doctor, pharmacist or healthcare provider before use if you are taking:

- Tetracycline antibiotics (used to treat infections) as Nativa Complex® Multi-Defence contains zinc, which may reduce the absorption of antibiotics. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after Nativa Complex® Multi-Defence or similar supplements;
- blood thinners (anticoagulant - or antiplatelet medication) e.g. warfarin as Nativa Complex® Multi-Defence contains a high dose of vitamin C, which may reduce the response to warfarin, possibly by causing diarrhoea and reducing warfarin absorption;
- hormonal contraceptives as vitamin C may increase blood levels of estrogens;
- fluphenazine (antipsychotic medication) as vitamin C may decrease levels of fluphenazine;
- indinavir (antiretroviral therapy) e.g. crixivan as vitamin C may decrease levels of indinavir;
- copper supplements as Nativa Complex® Multi-Defence contains zinc, which can inhibit copper absorption and decrease copper retention; or
- calcium supplements as Nativa Complex® Multi-Defence contains vitamin D, which can increase the absorption of calcium.

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

Taking Nativa Complex® Multi-Defence with food, drink and alcohol

There is no known interaction between contents of Nativa Complex® Multi-Defence and food, drink and alcohol.

Pregnancy and Breastfeeding and fertility

- It is not advisable to take Nativa Complex® Multi-Defence while pregnant.
- If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or relevant healthcare provider for advice before taking this medication.

Driving and using machines

Nativa Complex® Multi-Defence 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.

It is not always possible to predict to what extent Nativa Complex® Multi-Defence may interfere with your daily activities. Ensure that you do not engage in the above activities until you are aware of the measure to which Nativa Complex® Multi-Defence affects you.

3. How to take Nativa Complex® Multi-Defence

Do not share medicines with any other person.

Always take Nativa Complex® Multi-Defence exactly as described in this leaflet or as your healthcare provider has instructed you. You should check with your doctor or pharmacist regarding the recommended dosage if you are unsure.

The usual dose for adults 18 years and older is:

Take one (1) or two (2) capsules per day, after a meal with a glass of water.

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

Children:

Use in children under the guidance of a relevant doctor.

If you take more Nativa Complex® Multi-Defence than you should

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

If you forget to take Nativa Complex® Multi-Defence

Take your missed dose when you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and revert to your normal dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Nativa Complex® Multi-Defence

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® Multi-Defence can have side effects.

Not all side effects reported for Nativa Complex® Multi-Defence are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Nativa Complex® Multi-Defence, 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to Nativa Complex® Multi-Defence. You may need urgent medical attention or hospitalisation.

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 discomfort, constipation, diarrhoea, dry mouth, indigestion, heartburn, loss of appetite, 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 the SAHPRA via the “**Adverse drug reaction and quality**” website, found online at:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Nativa Complex® Multi-Defence.

5. How to store Nativa Complex® Multi-Defence

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- 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® Multi-Defence contains

Active ingredients	Per capsule	Per maximum daily dose (2 capsules)	% NRV* per maximum daily dose (2 capsules)
Calcium ascorbate	313,50 mg	627 mg	*
Providing Calcium (elemental)	28,87 mg	57,74 mg	3 %
Providing Vitamin C	253,84 mg	507,68 mg	*
Ascorbic acid (Vitamin C)	246,16 mg	492,32 mg	*
Providing total Ascorbic acid	500 mg	1000 mg	1000 %
Cholecalciferol (Vitamin D3)	12,5 µg (500 IU)	25 µg (1000 IU)	167 %
Selenium glycinate	1,25 mg	2,5 mg	*
Providing Glycine	1,23 mg	2,46 mg	*
Providing Selenium (elemental)	25 µg	50 µg	91 %
Zinc glycinate	62,5 mg	125 mg	*
Providing Glycine	50 mg	100 mg	*
Providing Zinc (elemental)	12,5 mg	25 mg	227 %

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

The other ingredients or excipients are: gelatine capsule (capsule constituents: bovine gelatine, colourants, titanium dioxide), magnesium stearate and microcrystalline cellulose.

Nativa Complex® Multi-Defence is sugar and preservative free.

What Nativa Complex® Multi-Defence looks like and contents of the pack

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

Holder of Certificate of Registration

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

Nativa Complex® Multi-Defence Professional Information may be obtained from the Nativa website (www.nativa.co.za).