

PROFESSIONAL INFORMATION
NATIVA COMPLEX® MULTIVITAMIN FOR MEN capsules

- Complementary Medicine.
- D.33.7 Complementary Medicines: Discipline Specific Traditional Claims – Combination Product
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
NATIVA COMPLEX® MULTIVITAMIN FOR MEN (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

Active Ingredients	Per capsule	Per maximum daily dose (2 capsules)	% NRV* per maximum daily dose (2 capsules)
Vitamin A acetate (Vitamin A)	1330 IU (400 µg RAE*)	2660 IU (800 µg RAE*)	89 %
Thiamine hydrochloride (Vitamin B1)	3,5 mg	7 mg	583 %
Riboflavin (Vitamin B2)	4 mg	8 mg	615 %
Nicotinamide (Vitamin B3)	9 mg	18 mg	113 %
Calcium-D pantothenate (Vitamin B5)	6 mg	12 mg	240 %
Pyridoxine hydrochloride (Vitamin B6)	5 mg	10 mg	588 %
Folic acid (Vitamin B9)	100 µg	200 µg	50 %
Cyanocobalamin (Vitamin B12)	2,5 µg	5 µg	208 %
Ascorbic acid (Vitamin C)	50 mg	100 mg	100 %
Cholecalciferol (Vitamin D3)	100 IU (2,5 µg)	200 IU (5 µg)	33 %
Tocopheryl acetate (Vitamin E)	14 IU (10 mg α-TE*)	28 IU (20 mg α-TE*)	133 %
D-biotin (Vitamin H)	30 µg	60 µg	200 %
Boron AAC**** providing Boron (elemental)	10 mg 0,5 mg	20 mg 1 mg	***
Calcium carbonate providing Calcium (elemental)	125 mg 50 mg	250 mg 100 mg	8 %
Chromium polynicotinate providing Chromium (elemental)	0,21 mg 25 µg	0,42 mg 50 µg	143 %
Copper AAC**** providing Copper (elemental)	5 mg 0,5 mg	10 mg 1 mg	111 %
Ferrous fumarate providing Iron (elemental)	9,13 mg 3 mg	18,26 mg 6 mg	33 %
Magnesium oxide providing Magnesium (elemental)	41,46 mg 25 mg	82,92 mg 50 mg	12 %
Selenium AAC**** providing Selenium (elemental)	3,75 mg 75 µg	7,5 mg 150 µg	273 %
Zinc AAC**** providing Zinc (elemental)	62 mg 12,5 mg	124 mg 25 mg	227 %
Eleutherococcus senticosus (Rupr. & Maxim.) Maxim. (Siberian ginseng/Eluthero) [rhizome, 10:1 extract providing 500 mg dried herb equivalent]	50 mg	100 mg	***
Serenoa (W. Bartram) Small (Saw palmetto) [fruit, 4:1 extract providing 200 mg dried herb equivalent]	25 mg	50 mg	***
Pinus pinaster Alton (Pine) [bark, 4:1 extract providing 50 mg dried herb equivalent]	12,5 mg	25 mg	***
Vitis vinifera L. (grape seed) [seed, extract standardised to 95 % proanthocyanidins]	12,5 mg	25 mg	***

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

*Retinol Activity Equivalents.

**D-alpha-Tocopherol Equivalents.

***NRV not established.

****Amino Acid Chelate.

Nativa Complex® Multivitamin for Men is sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, gelatine hard.
Nativa Complex® Multivitamin for Men capsules are light blue.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nativa Complex® Multivitamin for Men capsules is a general daily supplement specifically formulated for men. It can assist the body with antioxidant - immune function - and energy support. The formula contains zinc, selenium, boron, Pine, Saw palmetto and Siberian ginseng/Eluthero in quantities targeted to support health specific to men.

Efficacy of support may vary between users.

4.2 Posology and method of administration

The recommended daily dosage is

Adults:

Two (2) capsules per day, 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).

4.3 Contraindications

- Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients of Nativa Complex® Multivitamin for Men (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- Must not be given to patients with high blood pressure as Nativa Complex® Multivitamin for Men contains Siberian ginseng.
- Must not be given to patients suffering from liver disease or have peptic ulcer disease as Nativa Complex® Multivitamin for Men contains nicotinamide.
- Must not be given to patients known to have cobalamin or cobalt hypersensitivity as Nativa Complex® Multivitamin for Men contains vitamin B12.
- Must not be given to patients who are taking Retinoids as Nativa Complex® Multivitamin for Men contains vitamin A (see 4.5).
- Nativa Complex® Multivitamin for Men is formulated for men only. Not suitable for use in women, children or adolescents as it contains Siberian ginseng and Saw palmetto.
- 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 any type of acute infection should use the product with caution as Siberian ginseng/Eluthero may have influence on the condition.
- Use with caution in patients with a history of non-melanoma skin cancer as Nativa Complex® Multivitamin for Men contains selenium.
- Patients with a history of oxalate kidney stones should avoid high doses of vitamin C due to increased risk of kidney stone formation.
- Patients with bleeding disorders or taking anticoagulants/blood thinners, diabetic medication or immune suppressant medication should use this product with caution (see 4.5).
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.
- Products containing herbal ingredients may interact with some medication.
- Patients should discontinue use at least 2 weeks before elective surgical procedures.

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® Multivitamin for Men capsules, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Pine bark - grape seed - Siberian ginseng/Eluthero and saw palmetto extract, vitamin A, vitamin B3, vitamin E, magnesium and selenium	Blood thinners (anticoagulant – or antiplatelet medication) e.g. Warfarin	May have a blood thinning effect increasing the risk of bleeding.
Siberian ginseng/Eluthero - and pine bark extract and chromium	Antidiabetes medication	Might lower blood glucose levels resulting in additive effects with antidiabetic agents increasing the risk of hypoglycemia.
Grape seed and pine bark extract and selenium	Immunosuppressants e.g. Cyclosporine	May decrease absorption therefore separate doses by at least two (2) hours.

Vitamin A, vitamin B2, vitamin E and 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® Multivitamin for Men capsules or similar supplements.
Vitamin A	Retinoid drugs	Could have additive toxic effects when taken with vitamin A supplements. Advise patients taking Retinoids to avoid vitamin A supplements.

4.6 Fertility, pregnancy and lactation

Pregnancy

This product is indicated for men. Safety of most of the ingredients for use during pregnancy has not been established. Saw palmetto and vitamin A are specifically contraindicated, therefore this product should not be used in patients who are pregnant.

Breastfeeding

This product is indicated for men. Safety of most of the ingredients for use during lactation (breastfeeding) has not been established. Saw palmetto and vitamin A are specifically contraindicated, therefore this product should not be used if patients are lactating (breastfeeding).

Fertility

There are no known effects of Nativa Complex® Multivitamin for Men capsules on fertility.

4.7 Effects on the ability to drive and use machines

Based on the side effect profile, Nativa Complex® Multivitamin for Men capsules should not affect the ability to drive or operate machinery.

4.8 Undesirable effects

Nativa Complex® Multivitamin for Men capsules 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)
- not known (cannot be estimated from the available data)

Adverse events table		
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.
Nervous system disorders	Not known	Headaches dizziness, insomnia and fatigue.
Gastrointestinal disorders	Not known	Abdominal discomfort, - pain, - cramps and - fullness, constipation, diarrhoea, dyspepsia, heartburn, nausea, vomiting, halitosis, belching, flatulence and dry mouth.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (skin rash and itching).
Musculoskeletal and connective tissue disorders	Not known	Weakness, muscle - and back pain.

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_ADRF1_v6.1_27-Jan-2020.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.

Excessive dosage of vitamin A may lead to hypernatraemias. Due allowance should always be made for intake of these vitamins from other sources.

Vitamin D intoxication can occur when vitamin D supplements are taken orally in excessive doses.

Treatment

If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D.33.7 Complementary Medicines: Discipline Specific Traditional Claims – Combination product

Pharmacotherapeutic classification: Vitamins and other combinations

ATC code: A11JC

Eleutherococcus senticosus (Rupr. & Maxim.) Maxim.

(Siberian ginseng/Eluthero)

Most of medicinal actions of Siberian ginseng are credited to the bioactive eleutherosides, a group of liposoluble phenylpropanoid and Iginin glycosides found in the roots and stems, including sesamin, syringaresinol, schisandrin, and syringin. Siberian ginseng is typically used as an adaptogen.

Pinus pinaster Alton (Pine)

Pine bark extract has been shown to have angiotensin-converting enzyme inhibiting activity, vasorelaxant activity and the ability to enhance the microcirculation by increasing capillary permeability. Effects on the immune system and modulation of nitrogen monoxide metabolism have been shown. The extract contains flavonoid monomers.

Serenoa (W. Bartram) Small (Saw palmetto)

Saw palmetto has anti-proliferative and anti-inflammatory properties binding to pharmacological receptors existing in the lower urinary tract. Via the inhibition of 5α-reductase I and II and inhibition of binding of dihydrotestosterone (DHT) to the cytosolic androgen receptors saw palmetto has an anti-androgenic effect.

Vitis vinifera L. (grape seed)

Grape seed extract is a source of antioxidants, it contains phenolic compounds including oligomeric proanthocyanidins (OPCs), proanthocyanidins, flavonols, and polyflavan-3-ols.

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.

B Vitamins

B vitamins are essential nutrients required for normal body functioning and optimal health. They have integral roles in cellular functioning, acting as co-enzymes in a vast array of catabolic and anabolic enzymatic reactions.

5.2 Pharmacokinetic properties

Eleutherococcus senticosus (Rupr. & Maxim.) Maxim.

(Siberian ginseng/Eluthero)

Insufficient information available on the pharmacokinetics of Siberian ginseng/Eluthero.

Pinus pinaster Alton (Pine)

Insufficient information available on the pharmacokinetics of pine bark extract.

Serenoa (W. Bartram) Small (Saw palmetto)

Limited information available on the pharmacokinetics of saw palmetto.

Absorption: Peak plasma concentration of 2,6 mg/L at 1,5 hours following intake was reported after a single dose of 320 mg saw palmetto extract.

Distribution: Unknown

Excretion: A half-life of 19 hours was reported for saw palmetto.

Vitis vinifera L. (grape seed)

Limited information available on the pharmacokinetics of grape seed extract.

Absorption: Proanthocyanidins and flavonoids from grape seed extract are absorbed and distributed into serum within two to three hours of ingestion.

Distribution: Proanthocyanidins and flavonoids from grape seed extract can be detected in serum within two to three hours of ingestion.

Metabolism: Polyphenols are metabolized to phenolic acids by colonic microbiota.

Elimination: Antrocyanins and phenolic acids formed from polyphenols are excreted in the urine.

Vitamins and minerals

The combination of vitamins and minerals is typical of a normal diet. Therefore, the pharmacological metabolism and fate of Nativa Complex® Multivitamin for Men capsules is anticipated to be similar.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Gelatine capsule (capsule constituents: bovine gelatine, colorants, titanium dioxide)
Colloidal silicon dioxide
Tapioca Starch

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.
- Keep in original packaging until required for use.

6.5 Nature and contents of container

Nativa Complex® Multivitamin for Men capsules are light blue.

Nativa Complex® Multivitamin for Men capsules is available in a white high density polyethylene plastic container with a blue flip-top cap. It contains 60 capsules 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
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

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

May 2022