**PROFESSIONAL INFORMATION**
**NATIVA COMPLEX® PROSTATE SUPPORT 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® PROSTATE SUPPORT (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) |
|---|---|---|---|
| *Serenoa repens* spp. (Saw palmetto) [fruit, as extract standardised to 25 % fatty acids] | 100 mg | 200 mg | * |
| *Urtica dioica* L. (Stinging nettle) [leaf, 20:1 extract providing 2 g of dried herb equivalent] | 100 mg | 200 mg | * |
| *Pinus pinaster* spp. (Pine) [bark, 4:1 extract providing 200 mg of dried herb equivalent] | 50 mg | 100 mg | * |
| *Vitis vinifera* L. (Grape) [seed, as extract standardised to 95 % proanthocyanidins] | 50 mg | 100 mg | * |
| Phytosterols | 20 mg | 40 mg | * |
| Lycopene | 0,5 mg | 1 mg | * |
| Zinc gluconate<br>Providing Zinc (elemental) | 52,28 mg<br>7,5 mg | 104,56 mg<br>15 mg | 136 % |
| Selenium AAC**<br>Providing Selenium (elemental) | 1,5 mg<br>0,03 mg | 3 mg<br>0,06 mg | 0,1 % |

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

## 3. PHARMACEUTICAL FORM
Capsule, gelatine hard.
Nativa Complex® Prostate Support capsules are light blue.

## 4. CLINICAL PARTICULARS
### 4.1 Therapeutic indications
Nativa Complex® Prostate Support is a herbal supplement which contain ingredients to support men's health, reproduction and general prostate function, including urologic symptoms. Nativa Complex® Prostate Support provides anti-inflammatory and antioxidant support. For a diagnosis or if symptoms persist or worsen consult a relevant medical practitioner. Efficacy of support may vary between users.
### 4.2 Posology and method of administration
The recommended daily dosage is
*Adult males 18 years and older:*
One (1) capsule in the morning and one (1) capsule in the evening with a glass of water, after a meal.
Advise the patient to not take dosage at the same time as other medications (see **4.5**).
Advise the patient to discontinue use at least 2 weeks before elective surgical procedures (see **4.4**).
### 4.3 Contraindications
- Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients of Nativa Complex® Prostate Support (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- This product is formulated for men only and is not suitable for use in women, children or adolescents.
- Patients taking any chronic medication should not use this product without consulting their medical practitioner.
### 4.4 Special warnings and precautions for use
- Advise the patient to consult a healthcare provider prior to use if diagnosed or suspected to suffer from prostate cancer.
- Patients with a history of non-melanoma skin cancer should use this product with caution and avoid long-term use as Nativa Complex® Prostate Support contains selenium.
- Patients with bleeding disorders or taking anticoagulants/blood thinners or anti-platelet medication should consult a relevant healthcare provider before use as Nativa Complex® Prostate Support contains stinging nettle, pine and selenium (see **4.5**).
- Patients taking diabetic medication or immune suppressant medication should consult a relevant healthcare provider before use as Nativa Complex® Prostate Support contains pine (see **4.5**).
- Advise the patient to consult a healthcare provider if symptoms persist or worsen.
- Advise the patient to discontinue use at least 2 weeks before elective surgical procedures due to the influence of Nativa Complex® Prostate Support on bleeding time as it contains pine.
- Advise patients not to exceed the daily recommended dose.
- Advise patients not to use after the date of expiry.
- Products containing herbal ingredients may interact with some medication.

**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® Prostate Support capsules, see below interactions with individual ingredients.

| Active ingredient | Medicine | Description |
|---|---|---|
| Saw palmetto, stinging nettle, pine, grape seed, tomato and selenium | Blood thinners (anticoagulant or antiplatelet medication) e.g., warfarin, clopidogrel | Stinging nettle may decrease the effects of anticoagulants while selenium and pine may have a blood thinning effect, increasing the risk of bleeding. |
| Stinging nettle, pine and zinc | Antidiabetic medication | Concomitant use may have additive effects. |
| Stinging nettle | Diuretic medication | Concomitant use may have additive effects. |
| Stinging nettle | Lithium | May reduce excretion and increase levels of lithium. |
| Saw palmetto | Contraceptive medication and oestrogens | May have antiestrogenic effects and interfere with contraceptive medication and oestrogens. |
| Pine, zinc and selenium | Immunosuppressant medication | May decrease the effectiveness of immunosuppressant therapy. |
| Zinc | Antibiotics | Nativa Complex® Prostate Support 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® Prostate Support capsules or similar supplements. |

### 4.6 Fertility, pregnancy and lactation
**Pregnancy**
This product is formulated for men only. Saw palmetto and stinging nettle are specifically contraindicated, therefore this product should not be used in patients who are pregnant.
**Breastfeeding**
This product is formulated for men only. Saw palmetto is specifically contraindicated, therefore this product should not be used if patients are lactating (breastfeeding).
**Fertility**
There are no known effects of Nativa Complex® Prostate Support capsules on fertility.
### 4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Nativa Complex® Prostate Support capsules should not affect the ability to drive or operate machinery. It is not always possible to predict to what extent Nativa Complex® Prostate Support may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Nativa Complex® Prostate support affects them.
### 4.8 Undesirable effects
Nativa Complex® Prostate Support 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<1/1,000)
- 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 (skin rash and itching) or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria and itching. |
| Nervous system disorders | Not known | Headaches, dizziness, vertigo, insomnia, and fatigue. |
| Respiratory, thoracic and mediastinal disorders | Not known | Rhinitis. |
| Gastrointestinal disorders | Not known | Abdominal discomfort, - cramps and - pain, diarrhoea, difficulty swallowing, heartburn, constipation, nausea, vomiting and metallic taste. |
| Skin and subcutaneous tissue disorders | Not known | Hypersensitivity reaction (skin rash and itching). |
| Musculoskeletal and connective tissue disorders | Not known | Arthralgia (joint pain). |
| Reproductive system and breast disorders | Not known | Decreased libido. |

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://www.sahpra.org.za/Publications/Index/8 or via the "**Adverse drug reaction and product quality reporting**" website found online at: https://www.sahpra.org.za/Publications/Index/8.
### 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.
**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: Herbal and other combinations
ATC code: Not available

*Serenoa repens* spp. (saw palmetto)
The lipid fraction of saw palmetto contains volatile oils and fatty oils. Saw palmetto has antiandrogenic, antiproliferative, and anti-inflammatory properties.

*Urtica dioica* L. (stinging nettle)
Stinging nettle leaf contains several nutrients and active constituents including vitamin C, carotene, vitamin K, potassium, magnesium and calcium. Beta-sitosterol, lectins, flavonoids (quercetin, rutin and kaempferol) and others are also found in the leaf. Some clinical research has indicated that stinging nettle may improve peak urinary flow rate and symptom scores, as compared to placebo.

*Pinus pinaster* spp. (pine)
Pine contains several active constituents including flavonoid monomers such as catechin, epicatechin, and taxifolin as well as condensed proanthocyanidins and phenolic acids and their glucosides and glucose esters. Extracts of pine have been shown to have various modulating properties including anti-inflammatory, antioxidant and antiallergic effects.

*Vitis vinifera* L. (grape)
Grape seed extracts are rich in phenolic compounds, fatty acids, and vitamins. It has a high antioxidant potential with beneficial effects including protection against oxidative damage in cells, the modulation of antioxidant enzyme expression and anti-inflammatory effects.

Phytosterols
Phytosterols are plant-derived fatty compounds (steroids) representing the largest portion of unsaponifiable matter in plant lipids. A wide number of studies have reported on the pharmacological effects of phytosterols including; acting as chemopreventive, anti-inflammatory, antioxidant, antidiabetic, and antiatherosclerotic agents.

**Solanum lycopersium** L. (tomato)
Lycopene is a carotenoid synthesised by plants and microorganisms and is found in foods such as tomatoes. Lycopene functions as a potent antioxidant and also has anti-inflammatory, antineoplastic and antiplatelet effects.

Zinc
Zinc is a biologically essential trace element which functions as a cofactor in numerous biological processes including DNA, RNA, and protein synthesis. Zinc is present in more than 300 enzymes and plays a role in reproduction, immune function, wound healing, blood clotting, thyroid hormone function and insulin action. Zinc supplementation has shown to reduce inflammatory markers, including C-reactive protein, high-sensitivity C-reactive protein, tumour necrosis factor alpha, interleukin 6, malondialdehyde and neutrophils.

Selenium
Selenium is a major component of the glutathione peroxidase enzyme system. This system protects intracellular structures from oxidative damage.
### 5.2 Pharmacokinetic properties
*Serenoa repens* spp. (saw palmetto)
Insufficient information available.

*Urtica dioica* L. (stinging nettle)
Insufficient information available.

*Pinus pinaster* spp. (pine)
Absorption: Following oral intake of a standardised extract of pine, at least five known constituents can be detected in plasma starting within 30 minutes of ingestion. These constituents include ferulic acid, catechin, caffeic acid, taxifolin, and M1 (delta-(3,4-dihydroxy-phenyl)-gamma-valerolactone).
Metabolism: Constituents of pine extract are metabolised through glucuronide and sulphate conjugation.
Excretion: Ferulic acid and taxifolin conjugates of a standardised extract of pine are excreted in urine within 18-24 hours. Conjugated metabolites of the procyanidin fraction are excreted within 28-34 hours.

*Vitis vinifera* L. (grape)
Absorption: Proanthocyanidins and flavonoids from grape seed extract are absorbed within 2-3 hours of ingestion.
Distribution: Proanthocyanidins and flavonoids from grape seed extract are distributed into serum.
Metabolism: Polyphenols are metabolized to phenolic acids by colonic microbiota.
Elimination: Anthocyanins and phenolic acids formed from polyphenols are excreted in the urine.

Phytosterols
Insufficient information available.

Lycopene
Absorption: Since lycopene is fat soluble, it is absorbed into intestinal micelles made up of bile salts, cholesterol, and fatty acids. These are transported to the intestinal wall, where lycopene is absorbed by passive diffusion or with the help of a cholesterol membrane transporter into the enterocytes.
Distribution: Lycopene is packed into chylomicrons in the enterocytes along with other lipids, which are subsequently carried through the lymphatic system before being released into the blood. The range of the average plasma lycopene concentrations is 0,22 to 1,06 µmol/L. Age and levels are inversely associated, with patients over 80 years old having the lowest levels.
Low-density lipoproteins are the main carriers of lycopene in the blood. High quantities are found in the testicles, liver, prostate, adrenal glands, and ovaries, whereas lower concentrations are found in the kidneys, lungs, and ovaries.

Zinc
Absorption: Zinc is mostly absorbed in the small intestine, particularly the jejunum and may be influenced by dietary factors.
Distribution: More than 85% of total zinc in the body is found in skeletal muscle and bone. Plasma zinc is tightly regulated at a concentration of approximately 10 to 15 µmol/L.
Metabolism: Research has shown zinc moves rapidly to the liver, followed by two component exponential loss patterns.
Excretion: They majority of zinc is excreted in the faeces, with a small amount eliminated in the urine.

Selenium
Absorption: Most forms of selenium are efficiently absorbed in the gastrointestinal tract. Subsequent metabolism depends on the form in which they are present in plasma. Selenomethionine, selenocysteine, selenate, and selenite enter the selenide pool and from here the selenium is either used for selenoprotein synthesis or excreted in the urine as a selenosugar.
Distribution: The kidney accumulates the highest level of selenium and is the major source of plasma glutathione peroxidase. Selenium travels via the gastrointestinal tract, crosses the intestinal barrier, enters the bloodstream, and is then distributed to the various tissues of the body, including the skin.
Metabolism: Metabolism of selenium by the brain differs from other organs. At times of deficiency, the brain retains selenium to a greater extent.
Excretion: Selenium is excreted in the urine.

## 6. PHARMACEUTICAL PARTICULARS
### 6.1 List of excipients
Gelatine capsule (capsule constituents: bovine gelatine, colorant: brilliant blue FCF – FD&C blue 1, titanium dioxide)
Magnesium stearate
Colloidal silicon dioxide
Talc
### 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® Prostate Support capsules are light blue, hard gelatine capsules. Nativa Complex® Prostate Support capsules are 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
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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
April 2024