

PROFESSIONAL INFORMATION

NATIVA COMPLEX® BLADDER SUPPORT capsules

- Complementary Medicine.
- Discipline: D.33.7 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

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1. NAME OF THE MEDICINE

NATIVA COMPLEX® BLADDER SUPPORT (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Active Ingredients	Per capsule (maximum daily dose)
<i>Vaccinium macrocarpon</i> Aiton (Cranberry) [fruit, 600 - 800:1 extract standardised to 6 % proanthocyanidins providing 20 g of fresh fruit equivalent]	33,33 mg
<i>Hibiscus sabdariffa</i> L. (Hibiscus) [flower, extract standardised to 10 % polyphenols]	20 mg

Nativa Complex® Bladder Support is sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, gelatine hard.

Nativa Complex® Bladder Support capsules are maroon.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nativa Complex® Bladder Support is intended to supplement and assist the body with maintenance of bladder health and provides antioxidant protection of the urinary tract. Nativa Complex® Bladder Support contains high potency cranberry extract (equivalent to 20 g fresh fruit).

Efficacy of support may vary between users.

4.4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nativa Complex® Bladder Support is intended to supplement and assist the body with maintenance of bladder health and provides antioxidant protection of the urinary tract. Nativa Complex® Bladder Support contains high potency cranberry extract (equivalent to 10 g fresh fruit).

Efficacy of support may vary between users.

4.2 Posology and method of administration

The recommended daily dosage is

Adults 18 years and older:

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

4.3 Contraindications

- Must not be given to patients who are pregnant or breastfeeding as Nativa Complex® Bladder Support contains Hibiscus.
- Must not be given to patients with known hypersensitivity to any of the ingredients of Nativa Complex® Bladder Support (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- Patients taking any chronic medication should not use this product without consulting their medical practitioner.

4.4 Special warnings and precautions for use

- Patients who are taking blood thinners should consult a healthcare provider before use as Nativa Complex® Bladder Support contains Cranberry (see 4.5).
- Patients with a history of kidney stones should consult a healthcare provider before use as Nativa Complex® Bladder Support contains Cranberry extract.
- Do not exceed the daily recommended dose.
- Do not 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® Bladder Support, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Cranberry	Blood thinners (anticoagulant - or antiplatelet medication) e.g. warfarin	May have a blood thinning effect, increasing the risk of bleeding.
Hibiscus	Chloroquine	May reduce Chloroquine levels.
Hibiscus	Antidiabetic medication	May increase the risk of hypoglycaemia.
Hibiscus	Antihypertensive medication	May increase the risk of hypotension.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety of some of the ingredients for use during pregnancy has not been established (see 4.3), therefore this product should not be used in patients who are pregnant.

Breastfeeding

Safety of some of the ingredients for use during lactation (breastfeeding) has not been established (see 4.3), therefore this product should not be used if patients are lactating (breastfeeding).

Fertility

There are no known effects of Nativa Complex® Bladder Support on fertility.

4.7 Effects on the ability to drive and use machines.

Based on the side effect profile, Nativa Complex® Bladder Support should not affect your ability to drive or operate machinery.

4.8 Undesirable effects

Nativa Complex® Bladder 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 ($\geq 1/10$)
- common ($\geq 1/100$ to $< 1/10$)
- uncommon ($\geq 1/1,000$ to $< 1/100$)
- rare ($\geq 1/10,000$ to $< 1/1,000$)
- very rare ($< 1/10,000$)
- not known (cannot be estimated from the available data)

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.
Gastrointestinal Disorders	Not known	Abdominal discomfort, constipation, diarrhoea, flatulence and nausea.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (skin rash and itching).

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_ARF1_v5.1_27Jan2020.pdf 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 Discipline-Specific Traditional Claims – Combination Product

Pharmacotherapeutic classification: Urologicals

Vaccinium macrocarpon Aiton (Cranberry)

Cranberry contains proanthocyanidins, which interfere with bacterial adherence to the urinary tract epithelial cells.

Hibiscus sabdariffa L. (Hibiscus)

Hibiscus is commonly used for urinary tract infections as it exhibits antibacterial and antifungal activity.

5.2 Pharmacokinetic properties

Vaccinium macrocarpon Aiton (Cranberry)

Maximum levels of anthocyanins were detected in plasma 1-3 hours after ingestion. Elimination occurs through urine.

Hibiscus sabdariffa L. (Hibiscus)

Maximum levels of hibiscus metabolites detected in plasma 1,5 hours after ingestion. Elimination occurs through urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate

Gelatine capsule (capsule constituents: bovine gelatine, colorants, titanium dioxide)

Microcrystalline cellulose

Colloidal silicon dioxide

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® Bladder Support are maroon capsules.

Nativa Complex® Bladder Support capsules are available in a white high density polyethylene plastic container with a maroon flip-top cap. It contains 30 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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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

August 2023