

PROFESSIONAL INFORMATION

NATIVA COMPLEX® BLADDER FIZZY

- Complementary Medicine
- D33.7 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

[S0]

1. NAME OF THE MEDICINE

NATIVA COMPLEX® BLADDER FIZZY effervescent tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:

Active Ingredients	Per effervescent tablet	Per two effervescent tablets (maximum daily dose)
<i>Vaccinium macrocarpon</i> Aiton (cranberry) [fruit, extract 600 – 800:1 extract standardised to 6 % proanthocyanidins providing 15 g of fresh fruit equivalent]	25 mg	50 mg
D-mannose	500 mg	1000 mg

Nativa Complex® Bladder Fizzy contains sweeteners: acesulfame K (3,34 mg/effervescent tablet) and sucralose (6,66 mg/ effervescent tablet)..

Nativa Complex® Bladder Fizzy contains sugar: D-mannose 500 mg/effervescent tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablet. Nativa Complex® Bladder Fizzy effervescent tablets are pink.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nativa Complex® Bladder Fizzy is intended to supplement and assist the body with maintenance of bladder health and provide antioxidant protection of the urinary tract. Nativa Complex® Bladder Fizzy contains high potency cranberry extract (equivalent to 15 g fresh fruit) and D-mannose.

4.2 Posology and method of administration

Do not exceed the recommended daily dosage.

Adults 18 years and older:

Take two (2) effervescent tablets per day after a meal. Dissolve the effervescent tablet(s) in a glass of water. Drink the mixture as soon as the effervescing has stopped.

Use for at least 4 weeks to see beneficial effects.

4.3 Contraindications

Hypersensitivity to the active substance, *Vaccinium macrocarpon* Aiton (cranberry) or any of the ingredients of Nativa Complex® Bladder Fizzy (see 6.1 List of excipients).

4.4 Special warnings and precautions for use

- Do not use if known hypersensitivity or allergy exists towards any of the ingredients. If in doubt, consult your medical practitioner.
- Consult a healthcare provider before use if you have a history of kidney stones as Nativa Complex® Bladder Fizzy contains cranberry.
- Patients with bleeding disorders or taking anticoagulants/blood thinners or anti-platelet medication should use this product with caution (see 4.5).
- Patients with diabetes or taking antidiabetic medication should use this product with caution (see 4.5).

Porphyria

Safety has not been established.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed on Nativa Complex® Bladder Fizzy, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Cranberry	Blood thinners (anticoagulant or anti-platelet medication) e.g. warfarin	May have a blood thinning effect increasing the risk of bleeding.
Nativa Complex® Bladder Fizzy	Antacids	Concurrent use of antacids with citrates may result in systemic alkalosis.
Nativa Complex® Bladder Fizzy	Antacids	Concurrent administration of antacids with sodium bicarbonate may promote the development of calcium stones in patients with uric acid stones and may also cause hyponatremia.
D-mannose	Antidiabetic medication	Some research suggests that D-mannose might make blood sugar control more difficult in people with diabetes.

4.6 Fertility, pregnancy and lactation

Pregnancy

Use during pregnancy is not recommended, as safety during pregnancy has not been established.

Breastfeeding

Use during lactation is not recommended, as safety during lactation has not been established.

Fertility

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

4.7 Effects on the ability to drive and use machines.

Based on the side effect profile, Nativa Complex® Bladder Fizzy is not expected to 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.

4.8 Undesirable effects

Nativa Complex® Bladder Fizzy effervescent tablets 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 Events
Gastrointestinal Disorders	Not known	Abdominal discomfort, diarrhoea, nausea and bloating.
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria and itching.

If symptoms persist, or if any adverse reactions occur, 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. Health care 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

No case of overdosage has been reported.

Do not exceed the recommended daily dosage.

Treatment

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D33.7 Discipline-Specific Traditional Claims – Combination Product

Pharmacotherapeutic classification: Urologicals

Cranberry

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

5.2 Pharmacokinetic properties

Cranberry

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid
Colour (red beet juice powder)
Copolydione
Flavour (mixed berry)
Isomalt
Malic acid
Polyethylene glycol
Polyvinylpyrrolidone
Colloidal silicon dioxide
Sodium bicarbonate
Sorbitol
Tartaric acid
Nativa Complex® Bladder Fizzy contains sweeteners: acesulfame K (3,34 mg/effervescent tablet) and sucralose (6,66 mg/ effervescent tablet).

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.
- Keep container tightly closed.
- Replace cap firmly after use.
- Protect from light and moisture.
- Keep in original packaging until required for use.
- Do not use after the expiry date printed on the carton and bottle.

6.5 Nature and contents of container

Nativa Complex® Bladder Fizzy are round pink effervescent tablets.

Nativa Complex® Bladder Fizzy are available in a plastic tube container. The tube contains 10 effervescent tablets packed in a printed unit carton and includes a patient information leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF THE TEXT

August 2023