

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH VITAMIN C FIZZY 1000 MG effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:

Ascorbic Acid (Vitamin C)	1000 mg
Zinc Gluconate	67 mg
Providing Zinc (elemental)	8 mg
Cholecalciferol (Vitamin D3)	1000 IU (25 µg)

Contains sugar: sorbitol (600 mg) and isomalt (200 mg) per effervescent tablet.

Contains sweetener: sucralose / acesulfame K blend (25,5 mg) per effervescent tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets.

Flat, round bevelled-edged effervescent tablets with a citrus flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH VITAMIN C FIZZY 1000 MG contributes to the normal function of the immune system and supports the maintenance of good health.

4.2 Posology and method of administration

Adults and children 9 years and older: one (1) effervescent tablet daily, dissolved in a glass of water.

4.3 Contraindications

- Hypersensitivity to vitamin C, zinc, vitamin D3, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Patients with kidney disease or those who have a history of oxalate kidney stones.
- Patients with hypercalcaemia.

4.5 Interaction with other medicines and other forms of interaction

- Zinc may interfere with the effectiveness of antiretroviral medications due to reduced absorption.
- Zinc may reduce absorption of ciprofloxacin.
- Zinc forms an insoluble complex with penicillamine, interfering with its absorption and activity. Patients should take zinc and penicillamine at least 2 hours apart.
- Zinc forms various complexes with antibiotics in the gut, affecting the absorption and effectiveness of antibiotics.
- Zinc may lower blood glucose levels and may have additive effects in patients using antidiabetic medications.
- Vitamin C may reduce the activity of warfarin.
- Iron excretion induced by desferrioxamine is enhanced by the administration of vitamin C.
- Vitamin C may increase plasma estrogen levels of estrogen-containing oral contraceptives.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH VITAMIN C FIZZY 1000 MG does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: abdominal cramps, dyspepsia, esophagitis, heartburn, headache, diarrhoea, nausea, vomiting.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine 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://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.12 Multiple Substance Formulation.

5.1 Pharmacodynamic properties

LOCAL HEALTH VITAMIN C FIZZY 1000 MG contributes to the normal function of the immune system and supports the maintenance of good health.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH VITAMIN C FIZZY 1000 MG.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid
Sodium bicarbonate
Sorbitol
Isomalt
Flavouring
Crospovidone
Polyvinylpyrrolidone
Polyethylene glycol
Tartaric acid
Sucralose
Acesulfame K
Colourant (Sunset Yellow)

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Plastic tubes of 10 effervescent tablets, with a desiccant cap, packed into an outer carton. Pack size: 10 effervescent tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for CJ Distribution
23 Stag Road, Glen Austin, Johannesburg, South Africa
careline@cjsa.com
010 589 2729
www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

