

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.

**PATIENT INFORMATION LEAFLET
SCHEDULING STATUS**

SO

LOCAL HEALTH VITAMIN C FIZZY 1000 MG (effervescent tablets)

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.

Complementary Medicine: Multiple Substance Formulation (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.

Read all of this leaflet carefully because it contains important information for you.

LOCAL HEALTH VITAMIN C FIZZY 1000 MG is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH VITAMIN C FIZZY 1000 MG carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH VITAMIN C FIZZY 1000 MG with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What LOCAL HEALTH VITAMIN C FIZZY 1000 MG is and what it is used for.
2. What you need to know before you use LOCAL HEALTH VITAMIN C FIZZY 1000 MG.
3. How to use LOCAL HEALTH VITAMIN C FIZZY 1000 MG.
4. Possible side effects.
5. How to store LOCAL HEALTH VITAMIN C FIZZY 1000 MG.
6. Contents of the pack and other information.

1. What LOCAL HEALTH VITAMIN C FIZZY 1000 MG is and what it is used for

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

2. What you need to know before you use LOCAL HEALTH VITAMIN C FIZZY 1000 MG

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Do not use LOCAL HEALTH VITAMIN C FIZZY 1000 MG:

- If you are hypersensitive (allergic) to any of the ingredients listed in section 6.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH VITAMIN C FIZZY 1000 MG, especially if you have a medical condition.

Consult a healthcare practitioner prior to use:

- If you have kidney disease or have a history of oxalate kidney stones.
- If you have hypercalcemia.

Children and adolescents

LOCAL HEALTH VITAMIN C FIZZY 1000 MG is not recommended for individuals below the age of 9 years.

Other medicines and LOCAL HEALTH VITAMIN C FIZZY 1000 MG

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use if you are taking any of the following medications: antiretroviral medicines; ciprofloxacin; penicillamine; antibiotics; antidiabetic medications; warfarin; desferrioxamine; oral contraceptives.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using LOCAL HEALTH VITAMIN C FIZZY 1000 MG.

Driving and using machinery

No studies on the effects on the ability to drive or use of machinery have been performed. 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.

3. How to use LOCAL HEALTH VITAMIN C FIZZY 1000 MG

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH VITAMIN C FIZZY 1000 MG exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults and children 9 years and older

Take one (1) effervescent tablet daily, dissolved in a glass of water, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH VITAMIN C FIZZY 1000 MG can have side effects. Not all side effects reported for LOCAL HEALTH VITAMIN C FIZZY 1000 MG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH VITAMIN C FIZZY 1000 MG, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH VITAMIN C FIZZY 1000 MG and tell your doctor or pharmacist immediately, or go to the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH VITAMIN C FIZZY 1000 MG. You may need urgent medical attention or hospitalisation.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH VITAMIN C FIZZY 1000 MG.

5. How to store LOCAL HEALTH VITAMIN C FIZZY 1000 MG

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Store in the original container and keep the container tightly sealed.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH VITAMIN C FIZZY 1000 MG to your pharmacist.
- Do not dispose of unused LOCAL HEALTH VITAMIN C FIZZY 1000 MG in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH VITAMIN C FIZZY 1000 MG contains

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)

Other ingredients: citric acid, sodium bicarbonate, sorbitol, isomalt, flavouring, crospovidone, polyvinylpyrrolidone, polyethylene glycol, tartaric acid, sucralose, acesulfame K, colourant.

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

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

Presentation and identification of LOCAL HEALTH VITAMIN C FIZZY 1000 MG contains

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

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

SO

LOCAL HEALTH VITAMIN C FIZZY 1000 MG (bruistablette)

Elke bruistablet bevat:

Askorbiensuur (Vitamien C)	1000 mg
Sinkglukonaat	67 mg
Verskaf Sink (elementale)	8 mg
Cholekalsiferol (Vitamien D3)	1000 IU (25 µg)

Bevat suiker: sorbitol (600 mg) en isomalt (200 mg) per bruistablet.

Bevat versoeter: sukralose / acesulfame K mengsel (25,5 mg) per bruistablet.

Komplementêre Medisyne: Meervoudige Bestanddeel Formulasie (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

LOCAL HEALTH VITAMIN C FIZZY 1000 MG is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH VITAMIN C FIZZY 1000 MG versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH VITAMIN C FIZZY 1000 MG met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat LOCAL HEALTH VITAMIN C FIZZY 1000 MG is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH VITAMIN C FIZZY 1000 MG gebruik.
3. Hoe om LOCAL HEALTH VITAMIN C FIZZY 1000 MG te gebruik.
4. Moontlike nuwe-effekte.
5. Hoe om LOCAL HEALTH VITAMIN C FIZZY 1000 MG te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH VITAMIN C FIZZY 1000 MG is en waarvoor dit gebruik word

LOCAL HEALTH VITAMIN C FIZZY 1000 MG dra by tot die normale funksie van die immuunstelsel en ondersteun die handhawing van goeie gesondheid.

2. Wat u moet weet voordat u LOCAL HEALTH VITAMIN C FIZZY 1000 MG gebruik

'n Gevarieerde dieet is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling, sowel as geestelike en fisiese prestasie te behaal.

Moet nie LOCAL HEALTH VITAMIN C FIZZY 1000 MG neem nie:

- Indien u hipersensitief (allergies) is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH VITAMIN C FIZZY 1000 MG gebruik, veral as u 'n mediese toestand het.

Gebruik LOCAL HEALTH VITAMIN C FIZZY 1000 MG met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u niersiekte het of 'n geskiedenis van oksalaatnierstene het.
- Indien u hiperkalsemie het.

Kinders en adolessente

LOCAL HEALTH VITAMIN C FIZZY 1000 MG word nie aanbeveel vir individue onder die ouderdom van 9 jaar nie.

Die neem van LOCAL HEALTH VITAMIN C FIZZY 1000 MG en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige van die volgende medisyne gebruik: antiretrovirale medisyne; ciproflaxin; penisillamien; antibiotika; antidiabetiese medisyne; warfarin; desferrioksamien; orale voorbehoedmiddels.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH VITAMIN C FIZZY 1000 MG gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH VITAMIN C FIZZY 1000 MG nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH VITAMIN C FIZZY 1000 MG te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH VITAMIN C FIZZY 1000 MG presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 9 jaar en ouer

Neem een (1) bruistablet daaglik, opgelos in 'n glas water, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH VITAMIN C FIZZY 1000 MG kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH VITAMIN C FIZZY 1000 MG is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH VITAMIN C FIZZY 1000 MG, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

As een van die volgende gebeur, hou op met die gebruik van LOCAL HEALTH VITAMIN C FIZZY 1000 MG en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van u hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejeuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie teen LOCAL HEALTH VITAMIN C FIZZY 1000 MG gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Dikwels: abdominale krampe, dispepsie, esofagitis, sooi-brand, hoofpyn, diarree, naarheid, braking.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH VITAMIN C FIZZY 1000 MG.

5. Hoe om LOCAL HEALTH VITAMIN C FIZZY 1000 MG te bêre

- Beskerm teen vog en bêre by of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Stoor in die oorspronklike verpakking en hou die houder dig verseël.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH VITAMIN C FIZZY 1000 MG na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH VITAMIN C FIZZY 1000 MG in afvoertipe van rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH VITAMIN C FIZZY 1000 MG bevat

Elke bruistablet bevat:

Askorbiensuur (Vitamien C)	1000 mg
Sinkglukonaat	67 mg
Verskaf Sink (elementale)	8 mg
Cholekalsiferol (Vitamien D3)	1000 IU (25 µg)

Ander bestanddele: sitroensuur, natriumbikarbonaat, sorbitol, isomalt, geurmiddel, krospovidoon, polivinilpiroliid, polietileen-glikol, wynsteensuur, sukralose, acesulfame K, kleurstof.

Bevat suiker: sorbitol (600 mg) en isomalt (200 mg) per bruistablet.

Bevat versoeter: sukralose / acesulfame K mengsel (25,5 mg) per bruistablet.

Aanbieding en identifikasie van LOCAL HEALTH VITAMIN C FIZZY 1000 MG

Plastiekbuise van 10 bruistablette, met 'n droogmiddel deksel, verpak in 'n buite-karton.

Verpakkingsgrootte: 10 bruistablette.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685

Sorglyne: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.