

PROFESSIONAL INFORMATION

D 34.11 Vitamins. 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 500 MG tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Ascorbic Acid (Vitamin C) 500 mg

Contains sugar: 221 mg sorbitol per tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Small, round white to off-white tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH VITAMIN C 500 MG contains vitamin C, an essential vitamin for the maintenance of good health. It is an antioxidant which contributes to cell protection from free radical damage. It contributes to the normal function of the immune system and the nervous system. It assists with normal collagen formation and also to the reduction of tiredness and fatigue.

4.2 Posology and method of administration

Children 4-8 years: one (1) tablet daily.

Adults and children 9 years and older: one to two (1-2) tablets daily.

4.3 Contraindications

High sensitivity to any of the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Vitamin C may increase the risk of hyperoxaluria in patients with chronic kidney dysfunction. Large doses (>2 g daily) have been associated with an increased risk of oxalate kidney stones.
- Vitamin C is a strong reducing agent and interferes with diagnostic tests based on oxidation-reduction reactions. Large amounts of vitamin C may cause false increases in urine test results measured by copper reduction methods, and false decreases in results measure by glucose oxidase methods. Large amounts of vitamin C can cause a false-high blood glucose result when measured using a self-monitoring blood glucose device.
- Large amounts of vitamin C can cause haemolysis in individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency, and can increase the risk of oxalate stone formation in people with a history of oxalate kidney stones. The daily recommended dosage should not be exceeded.

4.5 Interaction with other medicines and other forms of interaction

- High doses of vitamin C may reduce the response to warfarin, possibly causing diarrhea and reducing warfarin absorption.
- Vitamin C may enhance iron excretion induced by desferrioxamine.
- Increases in plasma estrogen levels may occur under some circumstances when vitamin C is taken concurrently with oral contraceptives or hormone replacement therapy. Patients should be monitored for estrogen-related side effects.
- Concurrent use of vitamin C and fluphenazine may contribute to decreased fluphenazine levels.
- Concurrent use of vitamin C and protease inhibitors can reduce the effectiveness of the protease inhibitors.

4.6 Fertility, pregnancy and lactation

Vitamin C is likely safe when used within the recommended dosage. Large doses of vitamin C can cause gastrointestinal upset and newborn scurvy.

4.7 Effects on ability to drive and use machines

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 500 MG does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal

Frequent: gastrointestinal disturbances including diarrhea, nausea, vomiting, and abdominal pain.

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.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid is an antioxidant which contributes to cell protection from free radical damage. It contributes to the normal function of the immune system and the nervous system. It assists with normal collagen formation and also to the reduction of tiredness and fatigue.

5.2 Pharmacokinetic properties

Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues. Concentrations are higher in leucocytes and platelets than in erythrocytes and plasma. It is reversibly oxidised to dehydroascorbic acid; and metabolised to an inactive ascorbate-2-sulfate and oxalic acid which are excreted in the urine. Excess ascorbic acid (exceeding 100 mg daily) is rapidly eliminated unchanged in the urine. Ascorbic acid crosses the placenta and is distributed into breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol, magnesium stearate.

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.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

60 tablets in a white, PET plastic container and white screwcap lid.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjdsa.com

011 589 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 500 MG (tablets)

Each tablet contains:

Ascorbic Acid (Vitamin C) 500 mg

Contains sugar: 221 mg sorbitol per tablet.

Complementary Medicine: Vitamins (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 500 MG is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH VITAMIN C 500 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 500 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 500 MG is and what it is used for.
2. What you need to know before you use LOCAL HEALTH VITAMIN C 500 MG.
3. How to use LOCAL HEALTH VITAMIN C 500 MG.
4. Possible side effects.
5. How to store LOCAL HEALTH VITAMIN C 500 MG.
6. Contents of the pack and other information.

1. What LOCAL HEALTH VITAMIN C 500 MG is and what it is used for

Vitamin C is an essential vitamin for the maintenance of good health. It is an antioxidant which contributes to cell protection from free radical damage. It contributes to the normal function of the immune system and the nervous system. It assists with normal collagen formation and also to the reduction of tiredness and fatigue.

2. What you need to know before you use LOCAL HEALTH VITAMIN C 500 MG

Do not use LOCAL HEALTH VITAMIN C 500 MG:

- If you are allergic or sensitive to any of the ingredients listed in section 6.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH VITAMIN C 500 MG, especially if you have a medical condition.

Use LOCAL HEALTH VITAMIN C 500 MG with caution and consult a healthcare practitioner before use:

- If you suffer from chronic kidney disease; hyperoxaluria; kidney stones or have a history of oxalate kidney stones.
- If you have diabetes mellitus due to possible interference with glucose determinations.
- If you suffer from glucose-6-phosphate dehydrogenase deficiency.

Children and adolescents

LOCAL HEALTH VITAMIN C 500 MG is not recommended for children below the age of 4 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH VITAMIN C 500 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. LOCAL HEALTH VITAMIN C 500 MG may interact with the following medications: warfarin, desferrioxamine, estrogens, fluphenazine, protease inhibitors.

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 500 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 500 MG does not adversely affect their performance.

3. How to use LOCAL HEALTH VITAMIN C 500 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 500 MG exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Children 4-8 years:

Take one (1) tablet daily, or as recommended by a healthcare practitioner.

Adults and children 9 years and older:

Take one to two (1-2) tablets daily, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH VITAMIN C 500 MG can have side effects. Not all side effects reported for LOCAL HEALTH VITAMIN C 500 MG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH VITAMIN C 500 MG, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH VITAMIN C 500 MG and tell your doctor or pharmacist immediately, or go 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 500 MG. You may need urgent medical attention or hospitalisation.

- **Frequent:** gastrointestinal disturbances including abdominal pain, diarrhoea, nausea and 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 500 MG.

5. How to store LOCAL HEALTH VITAMIN C 500 MG

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH VITAMIN C 500 MG to your pharmacist.
- Do not dispose of unused LOCAL HEALTH VITAMIN C 500 MG in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH VITAMIN C 500 MG contains

Each tablet contains:

Ascorbic Acid (Vitamin C) 500 mg

Other ingredients: sorbitol, magnesium stearate.

Contains sugar: 221 mg sorbitol per tablet.

Presentation and identification of LOCAL HEALTH VITAMIN C 500 MG

60 small, round white to off-white tablets packed into a white plastic container.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 011 589 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 500 MG (tablette)

Elke tablet bevat:

Askorbiensuur (Vitamiën C) 500 mg

Bevat suiker: 221 mg sorbitol per tablet.

Komplementêre Medisyne: Vitamiene (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 500 MG is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH VITAMIN C 500 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 500 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 500 MG is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH VITAMIN C 500 MG gebruik.
3. Hoe om LOCAL HEALTH VITAMIN C 500 MG te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van LOCAL HEALTH VITAMIN C 500 MG.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH VITAMIN C 500 MG is en waarvoor dit gebruik word

Vitamiën C is 'n noodsaaklike vitamien om goeie gesondheid te handhaaf. Dit is 'n antioksidant wat bydra tot die beskerming van selle teen vrye radikale skade. Dit dra by tot die normale funksie van die immuunstelsel en die senuweestelsel. Dit help met normale kollageenvorming en ook om moegheid en tamheid te verminder.

2. Wat u moet weet voordat u LOCAL HEALTH VITAMIN C 500 MG gebruik

Moet nie LOCAL HEALTH VITAMIN C 500 MG neem nie:

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH VITAMIN C 500 MG gebruik, veral as u 'n mediese toestand het.

Gebruik LOCAL HEALTH VITAMIN C 500 MG met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u aan chroniese niersiekte ly; hiperoksalurie; nierstene of 'n geskiedenis van oksalaat nierstene het.
- Indien u diabetes mellitus het as gevolg van moontlike inmenging met glukosebepalings.
- Indien u ly aan glukose-6-fosfaat dehidrogenase tekort.

Kinders en adolessente

LOCAL HEALTH VITAMIN C 500 MG word nie aanbeveel vir kinders jonger as 4 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH VITAMIN C 500 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. LOCAL HEALTH VITAMIN C 500 MG kan interaksie hê met die volgende medisyne: warfarin, desferrioxamine, oestrogenen, flufenasien, protease-inhibeerders.

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 500 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 500 MG nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH VITAMIN C 500 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 500 MG presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Kinders 4-8 jaar:

Neem een (1) tablet daaglik, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

Volwassenes en kinders 9 jaar en ouer:

Neem een tot twee (1-2) tablette daaglik, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH VITAMIN C 500 MG kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH VITAMIN C 500 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 500 MG, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH VITAMIN C 500 MG en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevallen afdeling van u naaste hospitaal: swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejuuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH VITAMIN C 500 MG gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Dikwels:** gastrointestinale verstourings, insluitend buikpyn, diarree, naarheid en 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 500 MG.

5. Berging van LOCAL HEALTH VITAMIN C 500 MG

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BIJTE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH VITAMIN C 500 MG na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH VITAMIN C 500 MG in afvoertyppe of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH VITAMIN C 500 MG bevat

Elke tablet bevat:

Askorbiensuur (Vitamiën C) 500 mg

Ander bestanddele: sorbitol, magnesiumstearaat.

Bevat suiker: 221 mg sorbitol per tablet.

Aanbieding en identifikasie van LOCAL HEALTH VITAMIN C 500 MG

60 klein, ronde wit tot af-wit tablette verpak in 'n wit plastiekhouer.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorgly: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hiersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.