

PROFESSIONAL INFORMATION

D 34.12 Multiple Substance Formulation. 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 COLLAGEN capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Collagen Hydrolysate	400 mg
Ascorbic Acid (Vitamin C)	10 mg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to off-white, size 0 capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Collagen is a source of essential amino acids required for protein synthesis, collagen formation and the maintenance of good health. Vitamin C contributes to normal collagen formation for the normal function of blood vessels, bones, cartilage, skin, gums and teeth.

4.2 Posology and method of administration

Adults and children 6 years and older: two (2) capsules before bedtime.

4.3 Contraindications

Hypersensitivity 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

Patients with a medical condition should consult a healthcare practitioner prior to use.

4.5 Interaction with other medicines and other forms of interaction

Not all possible interactions may be included in this leaflet. Patients taking any other medicines, including complementary or traditional medicines, must consult a healthcare practitioner prior to use.

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

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 COLLAGEN does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal

Frequency unknown: gastrointestinal disturbances.

Immune System

Frequency unknown: hypersensitivity reactions.

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

Collagen is a source of essential amino acids required for protein synthesis, collagen formation and the maintenance of good health.

Vitamin C contributes to normal collagen formation for the normal function of blood vessels, bones, cartilage, skin, gums and teeth.

5.2 Pharmacokinetic properties

Collagen peptides are absorbed into the blood from the intestine and then distributed into other organs including the dermis, muscle, bones, liver, kidney and brain. Collagen peptides can remain in the dermis for up to two weeks. Part of the absorbed collagen peptides are further hydrolyzed into dipeptides, tripeptides, or amino acids by enzymes including peptidases, pancreatic proteases and small intestinal brush-border proteases.

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

Maize starch, silicon dioxide, talc, 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 capsules 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**

S0
LOCAL HEALTH COLLAGEN (capsules)

Each capsule contains:	
Collagen Hydrolysate	400 mg
Ascorbic Acid (Vitamin C)	10 mg

Sugar free

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

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH COLLAGEN 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 COLLAGEN is and what it is used for.
2. What you need to know before you use LOCAL HEALTH COLLAGEN.
3. How to use LOCAL HEALTH COLLAGEN.
4. Possible side effects.
5. How to store LOCAL HEALTH COLLAGEN.
6. Contents of the pack and other information.

1. What LOCAL HEALTH COLLAGEN is and what it is used for
Collagen is a source of essential amino acids required for protein synthesis, collagen formation and the maintenance of good health. Vitamin C contributes to normal collagen formation for the normal function of blood vessels, bones, cartilage, skin, gums and teeth.

2. What you need to know before you use LOCAL HEALTH COLLAGEN
Do not use LOCAL HEALTH COLLAGEN:

- 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 COLLAGEN, especially if you have a medical condition.

Children and adolescents
LOCAL HEALTH COLLAGEN is not recommended for children below the age of 6 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH COLLAGEN
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.

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 COLLAGEN.

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 COLLAGEN does not adversely affect their performance.

3. How to use LOCAL HEALTH COLLAGEN
Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH COLLAGEN 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 6 years and older:
Take two (2) capsules before bedtime, or as recommended by a healthcare practitioner.

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

Frequency unknown: hypersensitivity reactions, gastrointestinal disturbances.
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 COLLAGEN.

5. How to store LOCAL HEALTH COLLAGEN

- 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 COLLAGEN to your pharmacist.
- Do not dispose of unused LOCAL HEALTH COLLAGEN in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What LOCAL HEALTH COLLAGEN contains

Each capsule contains:	
Collagen Hydrolysate	400 mg
Ascorbic Acid (Vitamin C)	10 mg

Other ingredients: maize starch, silicon dioxide, talc, magnesium stearate.
Sugar free

Presentation and identification of LOCAL HEALTH COLLAGEN
60 white to off-white, size 0 capsules 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**

S0
LOCAL HEALTH COLLAGEN (kapsules)

Elke kapsule bevat:	
Kollageenhidrolisaat	400 mg
Askorbiensuur (Vitamien C)	10 mg

Suikervry

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

1. Wat LOCAL HEALTH COLLAGEN is en waarvoor dit gebruik word
Kollageen is 'n bron van essensiële aminosure wat benodig word vir proteïensintese, kollageenvorming en die handhawing van goeie gesondheid. Vitamien C dra by tot die normale vorming van kollageen vir die normale funksie van bloedvate, bene, kraakbeen, vel, tandvleis en tande.

2. Wat u moet weet voordat u LOCAL HEALTH COLLAGEN gebruik
Moet nie LOCAL HEALTH COLLAGEN 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 COLLAGEN gebruik, veral as u 'n mediese toestand het.

Kinders en adolessente
LOCAL HEALTH COLLAGEN word nie aanbeveel vir kinders jonger as 6 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH COLLAGEN 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.

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 COLLAGEN 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 COLLAGEN nie hul werkverrigting nadelig beïnvloed nie.

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

Volwassenes en kinders 6 jaar en ouer:
Neem twee (2) kapsules voor slaaptyd, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte
LOCAL HEALTH COLLAGEN kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH COLLAGEN is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewensde reaksies ervaar tydens die gebruik van LOCAL HEALTH COLLAGEN, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH COLLAGEN en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle 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, gejeuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH COLLAGEN gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

Dikwelsheid onbekend: hipersensitiwiteitsreaksies, gastroïntestinale versteurings.
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 COLLAGEN.

5. Berging van LOCAL HEALTH COLLAGEN

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

6. Inhoud van die verpakking en ander inligting
Wat LOCAL HEALTH COLLAGEN bevat

Elke kapsule bevat:	
Kollageenhidrolisaat	400 mg
Askorbiensuur (Vitamien C)	10 mg

Ander bestanddele: meliestysel, silikondioksied, talk, magnesiumstearaat.
Suikervry

Aanbieding en identifikasie van LOCAL HEALTH COLLAGEN
60 wit tot af-wit, grootte 0 kapsules verpak in 'n wit plastiekhouer.

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

Hierdie pamflet is laas hiersien in
Sal met registrasie deur SAHPRA toegeken word.

Registrasienuommer
Sal met registrasie deur SAHPRA toegeken word.