



Professional Information for ESSENTIALS COLLAGEN

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT)

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

ESSENTIALS COLLAGEN powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each scoop (7 g) contains:

Inulin	4 g
Hydrolysed collagen	2,5 g
SkinAx ^{2TM†} blend	150 mg
providing <i>Vitis vinifera</i> L. (Grape)	(114,7 mg)
[seed extract powder]	
Ascorbic acid	(16,5 mg)
providing vitamin C	(12 mg)
Zinc citrate	(16,5 mg)
providing zinc (elemental)	(4 mg)
<i>Cucumis melo</i> L. (French melon)	(2,3 mg)
[fruit, concentrate]	
Magnesium citrate	127,4 mg
providing magnesium (elemental)	20 mg
Ascorbic acid (Vitamin C)	6 mg
<i>Aloe vera</i> (L.) Burm. f. (Aloe)	4 mg
[dry inner leaf juice]	
Pyridoxine hydrochloride (Vitamin B ₆)	3 mg
Folic acid (Vitamin B ₉)	33 µg
D-Biotin (Vitamin B ₇)	2 µg

Excipients with known effect:

Contains sweetener (25 mg stevia per 7 g serving).

Contains sugar (129,5 mg sucrose per 7 g serving).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

Off-white powder with reddish speckles and a vanilla flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ESSENTIALS COLLAGEN is a combination complementary medicine that may assist to maintain healthy skin, joint health and inflammation.

4.2 Posology and method of administration

Adults: Take 1 scoop (7 grams) with a glass of water or juice, once daily. Do not exceed the recommended dosage.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in sections 2 and 6.1.
- Intestinal obstruction, inflammatory bowel disease (Crohn's disease, ulcerative colitis, appendicitis), ulcers, fever, undiagnosed gastrointestinal trouble or abdominal pain of unknown origin.
- Pregnancy or lactation.

4.4 Special warnings and precautions for use

Surgery:

ESSENTIALS COLLAGEN might interfere with blood glucose control and increase the risk of bleeding during and after surgical procedures. Patients should be advised to discontinue ESSENTIALS COLLAGEN at least 2 weeks prior to any surgical procedures (see section 4.5).

Long-term use:

The use of collagen as contained in ESSENTIALS COLLAGEN for 5 (five) months has been shown to be beneficial for joint pain and therefore its use should be undertaken in consultation with a relevant health care provider.

General:

If you have liver or kidney disease, a lazy bowel or if you have been instructed to follow a low protein diet, consult a relevant health care provider prior to use.

ESSENTIALS COLLAGEN may cause mild gastrointestinal disturbances.

Contains sugar:

ESSENTIALS COLLAGEN contains sugar (sucrose). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take ESSENTIALS COLLAGEN.

4.5 Interaction with other medicines and other forms of interaction

Cardiac or diuretic medicines:

Patients taking heart medications, corticosteroids, diuretics or other medicines or health products that may aggravate an electrolyte imbalance, should consult with a health care provider prior to using ESSENTIALS COLLAGEN.

Anticoagulant or antiplatelet medicines:

ESSENTIALS COLLAGEN may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects (see section 4.4).

Antidiabetic medicines:

Concomitant use of ESSENTIALS COLLAGEN with antidiabetic medicines or herbal supplements may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Antibiotics:

ESSENTIALS COLLAGEN may decrease the absorption of antibiotics. Doses should be separated by at least 2 hours prior, or 4 to 6 hours after taking ESSENTIALS COLLAGEN.

4.6 Fertility, pregnancy and lactation

ESSENTIALS COLLAGEN should not be taken during pregnancy or lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

ESSENTIALS COLLAGEN is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

ESSENTIALS COLLAGEN is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity/allergic reactions

Nervous system disorders:

Frequency unknown: headache

Gastrointestinal disorders:

Frequency unknown: gastrointestinal irritation, diarrhoea, heartburn, loss of appetite, nausea, vomiting, abdominal pain or cramps, dry mouth, dyspepsia, metallic taste, esophagitis, constipation, bloating, flatulence.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of ESSENTIALS COLLAGEN is important. It allows continued monitoring of the benefit/risk balance of ESSENTIALS COLLAGEN. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination Product

Mechanism of action:

Inulin helps support and maintain a healthy digestive system and helps to provide relief of irregular bowel movements.

Hydrolysed collagen helps to assist joint health or inflammation.

Grape seed extract provides antioxidants for the maintenance of good health and contributes to the maintenance of venous health.

Aloe has anti-inflammatory, antioxidant, detoxification and immune-boosting properties.

Magnesium helps to metabolise carbohydrates, fats and proteins. It also contributes to the development and maintenance of bones and teeth, tissue formation, and the maintenance of normal muscle function.

Zinc helps to maintain immune function and healthy skin.

Folic acid helps the body metabolise proteins, helps to form red blood cells and is a factor in the maintenance of good health.

Biotin plays a role in the maintenance of good health.

Vitamin B6 plays a role in the maintenance of good health and contributes to tissue formation.

Vitamin C is an antioxidant and plays a role in the maintenance of good health. It helps to metabolise fats and proteins and with tissue formation.

French melon has antioxidant and anti-inflammatory properties.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Citric acid (E330),

Flavourant (containing modified food starch, maltodextrin, vanilla flavour, sugar and triacetin), Silicon dioxide,

Stevia.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

Store at or below 25 °C.

6.4 Special precautions for storage

Store in a dry place.

Keep the bottle tightly closed.

Do not use if inner seal is missing or broken.

6.5 Nature and contents of container

White polyethylene terephthalate (PET) jar with a white polypropylene (PP) lid and a 15 mL scoop, containing 210 g powder.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6, Ground Floor
10 Church Street
Durbanville
7551
South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

September 2025