



PROFESSIONAL INFORMATION

COMPLEMENTARY 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

COLLAPRO™ BOVINE COLLAGEN (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Hydrolysed Collagen (Bovine) (Highly Functional)	500,00 mg
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Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Clear, size 00 hard gelatine capsules filled with a light beige powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

COLLAPRO™ BOVINE COLLAGEN is a health supplement that assists with joint health and inflammation. Collagen may improve skin, hair and nail condition, reduce joint pain, and improve bone density and the health of your gut lining.

4.2 Posology and method of administration

Posology

Adults 18 years and older: Take 5 capsules daily, split as desired, or as recommended by a healthcare practitioner.

Use of collagen for 5 (five) months has been shown to be beneficial, and its use should be undertaken in consultation with a relevant healthcare provider.

Not recommended for children under the age of 18 years.

Do not exceed the recommended dose.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Hypersensitivity to sulphites.

4.4 Special warnings and precautions for use

- Patients should take special care with COLLAPRO™ BOVINE COLLAGEN if they are currently taking any medication or if they are suffering from a medical condition.

4.5 Interaction with other medicines and other forms of interaction

No known interactions.

4.6 Fertility, pregnancy and lactation

Safety in fertility, 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 COLLAPRO™ BOVINE COLLAGEN does not adversely affect their performance.

4.8 Undesirable effects

COLLAPRO™ BOVINE COLLAGEN is generally well tolerated.

Gastrointestinal disorders

Frequency unknown: nausea, dyspepsia, diarrhoea, flatulence.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare 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

Class and category: Category D 34.3 Animal Extracts, Products and Derivatives

Collagen peptides have been shown to improve collagen synthesis. Collagen peptides have been shown to increase concentrations of certain collagen-derived dipeptides in the blood. These collagen-derived dipeptides may stimulate and/or protect cells in various connective tissues. Collagen helps with joint health and joint inflammation.

5.2 Pharmacokinetic properties

Collagen peptides are up to 90% absorbed within 12 hours of oral intake, due to their small size. Some collagen peptides are hydrolysed into dipeptides, tripeptides, or amino acids by enzymes such as peptidases, pancreatic proteases, and small intestinal brush-border proteases. Maximum serum concentrations of dipeptides and tripeptides are observed 1 – 2 hours after ingestion. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule:

Gelatine (bovine)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Store in a dry place away from direct sunlight and moisture.

Store in the original package until required for use.

6.5 Nature and contents of container

Clear, embossed glass jar with a black screw cap lid.

Pack size: 150 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

The Harvest Table (Pty) Ltd

Unit 1

8 Reed Place

Maxmead

South Africa

3610

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.