

**PROFESSIONAL INFORMATION**



**COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT**

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

**SCHEDULING STATUS**

S0

**1. NAME OF THE MEDICINE**

**COLLAPRO™ MARINE COLLAGEN (capsules)**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains:

Hydrolysed Collagen (Marine) (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 vegetable capsules filled with a light beige powder.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

COLLAPRO™ MARINE 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 fish.
- Hypersensitivity to sulphites.

#### **4.4 Special warnings and precautions for use**

- Patients should take special care with COLLAPRO™ MARINE 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™ MARINE COLLAGEN does not adversely affect their performance.

#### **4.8 Undesirable effects**

COLLAPRO™ MARINE 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:*

Vegetable Capsule

Hypromellose, carrageenan, 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.