

# PATIENT INFORMATION LEAFLET

## 1. SCHEDULING STATUS

Not Scheduled.

## 2. PROPRIETARY NAME (AND DOSAGE FORM)

### **SONTAL Marine Collagen Tripeptide (CAPSULES)**

Pack Size: 60 Vegetable Capsules

Each capsule contains 500 mg of 15% Tripeptide Collagen.

Contains No Excipients.

Sugar-free.

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

## 3. CLASSIFICATION

Category D: Complementary Medicine, Health Supplement 34.3 Single Ingredient Animal Derivative.

### **READ THIS ENTIRE LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU**

SONTAL Marine Collagen Tripeptide 60 Vegetable CAPSULES is available without a doctor's prescription.

Nevertheless, you need to use SONTAL Marine Collagen Tripeptide 60 Vegetable Capsules as directed to get the best results.

Keep this leaflet. You may need to read it again.

Do not share SONTAL COLLAGEN Tripeptide 60 Vegetable Capsules with any person.

Ask your pharmacist if you need more information or advice.

## 5. WHAT SONTAL COLLAGEN Tripeptide CONTAINS

The active ingredients are:

Each SONTAL Marine Collagen Tripeptide (CTP) capsule contains 500 mg standardised to **15% Morikol® Collagen Tripeptide** equivalent to 75mg tripeptide per capsule, every dose of 2 capsules contains 1000 mg peptides of which 150 mg Tripeptide.

(see 12. IMPORTANT INFORMATION ABOUT THE INGREDIENTS OF SONTAL Tripeptide)

## The other ingredients are:

Contains no additives.

Contains no excipients.

Sugar-free.

## 6. PHARMACOLOGICAL CLASSIFICATION

**Morikol® tripeptide** is digestion proof, absorbing intact through exclusive PEPT1 receptors in the intestines. Tripeptides have been found circulating in free form in the bloodstream and in tissue spaces, having shown chemotactic benefits similar to endogenous growth factors like platelet-derived, and basic fibroblast growth factors (PDGF and BFGF).

Furthermore, even dipeptides that are enzymatically cleaved from tripeptide by intestinal peptidases are shown to directly increase the proliferation of fibroblasts, (i.e. collagen synthesizing cells).

**Morikol® Collagen Tripeptide**, as a low molecular weight collagen peptide (LMWCP), has been the subject of several clinical and preclinical studies, within a dose range of 1-2g/day.

For **Morikol® Collagen Tripeptide** skin-promoting benefits, a low daily dose of 1g/day is proven to provide collagen rebuilding and anti-ageing properties to the skin.

As a joint-support ingredient, **Morikol® Collagen Tripeptide** benefit has been established at as low as 2 g/day. The below list of studies has been published on Morikol®.

- Do-Un K, et al. Oral Intake of Low-Molecular-Weight Collagen Peptide Improves Hydration, Elasticity, and Wrinkling in Human Skin: A Randomized, Double-Blind, Placebo-Controlled Study. *Nutrients*. 2018;10(826)
- Yamamoto S, et al. Effect of Collagen Tripeptide on Knee Osteoarthritis in Humans and Animals. *Pharmacometrics*. 2015;89 (5/6):115-124
- Pyun H-B, et al. Effects of Collagen Tripeptide Supplement on Photoaging and Epidermal Skin Barrier in UVB-exposed Hairless Mice. *Prev Nutr Food Sci*. 2012; 17: 245-253

## 7. UNIQUE BENEFIT OF SONTAL Tripeptide

Collagen Tripeptide (CTP) is referred to as the “ESSENTIAL AMINO ACID SEQUENCE”, it has a unique sequence of amino acids specific to collagen fibre and the very (tri-)peptide critical to the formation of collagen.

In clinical studies collagen tripeptide has been shown to;

- directly increase the proliferation of fibroblasts, (i.e. collagen synthesizing cells).
- be a direct substrate for skin tissue healing and regeneration.
- protect the skin from the photo-ageing effects of UV-B radiation
- protects skin from premature ageing

Collagen Tripeptide has a very low molecular weight of 300 Da, this characteristic makes CTP easy to absorb and highly bioavailable. Di- and Tripeptides from Morikol are absorbed intact increasing bioavailability at the target site where it is available to repair and rebuild damaged collagen tissue as bioactive peptides.

These characteristics have significantly increased the molecules' clinical value, thereby lowering the effective dose whilst delivering a higher clinical activity per dose compared to the standard 10 000 mg dosages offered by general hydrolysed collagen powders.

When comparing **general collagen powders** with **Morikol® Collagen Tripeptide**;

One daily dose of **10 000 mg** (10 g) of general collagen powder typically delivers 90% peptides of which <1% tripeptides per dose < **90 mg**.

**Morikol®** at a daily dose of **1 000 mg** (1 g) has a **minimum** concentration standard of 15% tripeptides per dose > **150 mg**.

The result is a **low convenient** daily dose of 1 000 mg or 2 x 500 mg capsules of **Morikol®** delivers 1,5 times (50%) more **Bioactive Collagen Tripeptides** than what general collagen powders deliver at 10 000 mg.

## 8. WHAT SONTAL Tripeptide ARE USED FOR

SONTAL COLLAGEN Tripeptide 60 Vegetable CAPSULES are primarily used for SKIN, JOINT and BONE health.

PRIMARY INDICATIONS for Skin Health

### Unique Benefits

- Protection against premature photoaging of the skin.
- Protection against the harmful UV radiation of the sun.

### Primary Benefits

- Promotes healthy skin
- Protects skin from oxidative stress
- Minimizes wrinkles and fine lines
- Improves skin hydration
- Reduces skin roughness

### Other Benefits

Dosage 2g: 4 x 500 mg = 2 000 mg Standardised at 15% Tripeptide = 300 mg tripeptides.

### Bone Health:

- Increase bone density
- Improve bone flexibility
- Reduces risk of fractures

### Joint Health:

- Decreases Joint pain
- Improve joint flexibility
- Improves mobility

## **Muscle Health:**

- Muscle Recovery
- Tendon integrity
- Ligament strength
- Recovery and prevention
- Injury recovery
- Surgery recovery
- Injury prevention

## **9. BEFORE YOU TAKE SONTAL Marine Collagen Tripeptide**

Do not take under the following conditions:

Known hypersensitivity or allergy to any ingredients in SONTAL Tripeptide. (see 5. **WHAT SONTAL Tripeptide CONTAINS**).

Collagen has been consumed by many people across the globe for many years and the safety of it or the by-products of its production have never presented any concerns for safety. Morikol® is produced with food-grade enzymes and is considered a safe product.

## **10. PREGNANCY AND BREASTFEEDING**

Consult with a healthcare practitioner.

## **11. DRIVING AND USING MACHINERY**

SONTAL Tripeptide does not affect the ability to drive or operate machinery.

## **12. IMPORTANT INFORMATION ABOUT THE INGREDIENTS OF SONTAL Marine Collagen Tripeptide**

**SONTAL MARINE Collagen Tripeptide contains Morikol®**, a patented standardised marine collagen of which 15% tripeptide delivers 150mg of collagen-specific tripeptide per 1 000 mg dose.

Marine Tripeptide Collagen, or CTP (Collagen Tripeptide), is a collagen hydrolysate with a tripeptide concentration of **more than 15%** versus general collagen powders which is **less than 1%**.

**SONTAL MARINE Collagen Tripeptide Capsules** contain **Morikol®** a 100% piscine-derived, collagen hydrolysate, concentrated to contain a minimum of 15% tripeptides in the highly bioavailable, tripeptide format Gly-X-Y, where X and Y most commonly include proline, hydroxyproline and alanine. **CTP** is the **ESSENTIAL AMINO ACID SEQUENCE** unique to collagen.

A Tripeptide is the bioactive component of any collagen powder, the higher the tripeptide density, the more bioactive molecules reach the target tissue in your body.

## **13. TAKING OTHER MEDICINES WITH SONTAL Tripeptide CAPSULES**

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

**No interactions are known.**

## **14. HOW TO TAKE SONTAL Tripeptide CAPSULES**

Do not share medicines that you are taking with any other person.

Always take SONTAL Marine Collagen Tripeptide Capsules exactly as the directions show. You should check with your doctor or pharmacist if you are unsure.

### **Directions for Use**

- Adults, take two (2) vegetable capsules containing 500mg each, daily or as prescribed by a healthcare practitioner.
- Take the capsules with a sufficient quantity of liquid (e.g. one glass of water).

Use in children under 18 years is not recommended.

## **15. IF YOU TAKE MORE THAN YOU SHOULD**

This product contains collagen amino acid peptides generally regarded as safe.

No known side effects from overdosing with SONTAL Marine Collagen Tripeptide Capsules have been recorded or reported.

## **16. IF YOU FORGET TO TAKE SONTAL Tripeptide CAPSULES**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take it at the next regularly scheduled time.

For optimum results, do not miss taking a dose regularly as directed.

## **17. POSSIBLE SIDE EFFECTS**

No known side effects for SONTAL Marine Collagen Tripeptide Capsules have been recorded or reported.

People have not experienced any side effects when taking SONTAL Marine Collagen Tripeptide Capsules.

Should your general health worsen or if you experience any untoward effects while taking SONTAL Marine Collagen Tripeptide Capsules please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet or if you experience any serious allergic reaction to SONTAL Marine Collagen Tripeptide Capsules, please inform your doctor or pharmacist.

## **18. WARNINGS AND SPECIAL PRECAUTIONS**

Keep out of reach of children.

## **19. STORING AND DISPOSING OF SONTAL Marine Collagen Tripeptide Capsules**

Store at or below 25°C, in the original packaging in a dry place. Protect from direct sunlight.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **20. STORE ALL MEDICINE OUT OF REACH OF CHILDREN**

Do not use it after the expiry date printed on the label or carton.

## **21. PRESENTATION OF SONTAL Marine Collagen Tripeptide Capsules**

The capsules are packed into a white plastic 300ml LDPE bottle containing 60 white Vegetable Capsules. The cap is a white plastic screw-on closure with an induction seal fixed to the rim of the bottle.

## **22. IDENTIFICATION OF SONTAL Tripeptide CAPSULES**

The body and cap of the capsules are opaque white.

## **23. REGISTRATION NUMBER**

To be allocated by Council upon registration.

## **24. STATEMENT**

This product has not been evaluated by SAHPRA and does not intend to diagnose, treat, cure or prevent any form of illness or disease and should not replace any medication.

A Patient Information Leaflet is available electronically online or can be sent to the consumer by mail, WhatsApp or other preferred methods.

Scan QR Code

## **25. NAME AND BUSINESS ADDRESS OF THE APPLICANT**

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## **26. DATE OF PUBLICATION**

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