

**PROFESSIONAL INFORMATION**
**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**

**BIOGEN COLLAGEN (Bovine Gelatine Capsules)**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

COMPOSITION: EACH CAPSULE CONTAINS:	PER 3 CAPSULE DOSAGE:	%NRV*
Hydrolysed Collagen	400,00 mg	1 200,00 mg
Ascorbic Acid (Vitamin C)	10,00 mg	30,00 mg 10

\*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).

Sugar Free.

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Bovine Gelatine Capsules.

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**

BIOGEN COLLAGEN helps in connective tissue formation and helps to assist joint health or joint inflammation.

**4.2 Posology and method of administration**
**Adults and children 6 years and older:**

Take three (3) capsules daily, or as recommended by your healthcare provider.

**4.3 Contraindications:**

- If you are allergic to any of the ingredients listed in 6.1.
- If you have a hypersensitivity to any of the excipients listed in 6.1.

**4.4 Special warnings and precautions for use**

Special care should be taken with BIOGEN COLLAGEN.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

**4.5 Interaction with other medicines and other forms of interaction**

Interactions are not expected. If you suffer from any serious ailments or conditions (such as liver or kidney disease), or if you are taking any prescribed medications. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

**4.6 Fertility, pregnancy and lactation**

Safety in pregnancy and lactation has not been established. If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

**4.7 Effects on ability to drive and use machines**

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN COLLAGEN does not adversely affect their performance.

**4.8 Undesirable effects**

Orally, BIOGEN COLLAGEN is well-tolerated but it can have side effects. Not all side effects reported for BIOGEN COLLAGEN are included in this leaflet.

Side effects can include:

*Frequency unknown:* hypersensitivity reactions; mild gastrointestinal disturbances.

Should your general health worsen or if you experience any untoward effects while taking this medicine, discontinue use immediately and consult your doctor, pharmacist or other healthcare provider for advice.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of BIOGEN COLLAGEN is important. It allows continued monitoring of the benefit/risk balance of BIOGEN COLLAGEN. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Adverse Drug Reaction Reporting Form, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

**4.9 Overdose**

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). In the event of overdose, treatment should be symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**

Category and class: D 34.12 Multiple substance formulation.

Complementary Medicine: Health supplement.

BIOGEN COLLAGEN helps in connective tissue formation and helps to assist joint health or joint inflammation.

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

Off-white capsule, Maize Starch, silicon dioxide, magnesium stearate.

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf Life**

24 Months.

**6.4 Special precautions for storage**

Store in a cool dry place, at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

**6.5 Nature and contents of container**

175 / 250 ml PET Container.

Pack sizes: 30 / 60 / 180 Bovine Gelatine Capsules.

**6.6 Special precautions for disposal and other handling**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Biogen,  
23 Stag Rd,  
Glen Austin,  
South Africa.

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.

<b>JOB:</b> BPS_Collagen 30s, 60s & 180s		<b>SIZE:</b> 245mm x 145mm	
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
<b>COLOUR:</b>		<b>FINISHING:</b>	
<input checked="" type="checkbox"/> K		<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing	
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			