

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 RE|NU COLLAGEN & SKIN****2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains:		%NRV
Omega-3 Providing	300,00 mg	
EPA (Eicosapentaenoic acid)	15,00 mg	
DHA (Docosahexaenoic acid)	9,00 mg	
Hydrolysed Collagen	50,00 mg	
Vitamin C (as Ascorbic acid)	50,00 mg	50 %
Vitamin A (as Vitamin A Acetate)	10,00 mg (5000 IU)	30 %
Zinc (as Zinc Sulphate Heptahydrate)	10,00 mg	167 %
Vitamin E (as Vitamin E Acetate)	7,50 mg TE	
Astaxanthin	4,00 mg	50 %
Copper (as Copper AAC)	2 500,00 µg	278 %
Biotin (as D-Biotin)	50,00 µg	167 %

Preservatives in the capsule shell:

Methyl paraben 0,8 %.

Propyl paraben 0,2 %.

Sugar free

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bovine gelatine capsule.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

BIOGEN RE|NU COLLAGEN & SKIN is indicated as an Amino acid, Vitamin and Mineral complex for advanced skin health and nourishment.

4.2 Posology and method of administration

Adults: Take 1 capsule daily with food, or as recommended by a healthcare practitioner.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients (see section 6.1).
- Pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

- Taking multiple supplements and multivitamins may cause a cumulative intake of certain nutrients/substances. It is therefore recommended that a healthcare provider is consulted prior to use.
- If you suffer from any serious ailments or conditions; or if you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.
- Consult a health care provider before use if you take blood-thinning medicines, are asthmatic with sensitivity to aspirin, or for use beyond three months.
- Usage should be avoided when taking immuno-suppressants, by patients with bleeding disorders, and by patients on 5-α-reductase inhibitors.
- 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

- Supplemental intake of certain ingredients may interfere with certain medicines and supplements, diseases and foods.
- If you are taking other medicines regularly, including complementary or traditional medicines, or start taking any additional medicines while taking this medicine, consult your healthcare provider for advice.
- Antibiotics: The concomitant use of zinc, as in BIOGEN RE|NU COLLAGEN & SKIN, with fluoroquinolones and tetracyclines reduces the absorption of these antibiotics. Advise patients to take these antibiotics 2 to 3 hours before or after taking BIOGEN RE|NU COLLAGEN & SKIN.
- Chelating agents: The use of zinc, as in BIOGEN RE|NU COLLAGEN & SKIN, with penicillamine reduces the absorption of penicillamine. Advise patients to separate doses by 2 to 3 hours.
- Phenylketonurics: It contains phenylalanine.
- Consult a healthcare practitioner before use if you have acidosis, atherosclerosis or methylene-tetra-hydrofolate reductase deficiency.
- Consult a healthcare practitioner before use if you have eosinophilia myalgia syndrome, liver disease or depression.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

BIOGEN RE|NU COLLAGEN & SKIN is not indicated for use during pregnancy or lactation. Consult a health care provider prior to use if you are of childbearing age, pregnant or breastfeeding.

Do not use BIOGEN RE|NU COLLAGEN & SKIN while pregnant or breastfeeding (see section 4.3).

4.7 Effects on ability to drive and use machines

BIOGEN RE|NU COLLAGEN & SKIN is unlikely to affect the ability to drive a vehicle or use machines. Caution is advised not to drive a vehicle or operate machinery until the effects of BIOGEN RE|NU COLLAGEN & SKIN are known.

4.8 Undesirable effects

BIOGEN RE|NU COLLAGEN & SKIN is generally well tolerated but may have side effects;

Immune system disorders:

Less frequent: hypersensitivity reactions

Frequency unknown: increased intake of Eicosapentaenoic acid may increase the risk for viral infections and some cancers.

Gastrointestinal disorders:

Less frequent: gastrointestinal disturbances including abdominal pain or cramping, indigestion, heartburn, nausea, diarrhoea.

Dermatologic:

Less frequent: skin reactions like rash, itching, sweating, hives, flushing, edema.

Cardiac disorders:

Frequency unknown: chest pain, angina, flushing.

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: <http://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

See section 4.8.

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

5. PHARMACOLOGICAL PROPERTIES**Category and class:**

Category D 34.12 Multiple substance formulation

An Amino acid, Vitamin and Mineral complex for advanced skin health and nourishment. Collagen Peptides, Vitamin C, Biotin and Copper are included for healthy skin and structure, collagen boosting and formation, while supporting connective tissue and wound healing. Omega-3 fatty acids may reduce inflammatory markers and also have antioxidant effects which assist in maintaining healthy skin. A unique combination of Antioxidants, Astaxanthin, Vitamin C and Vitamin E are useful nutrients in fighting cell-damaging free radicals, which can cause oxidative stress in the body and contribute to the premature ageing of cells. Antioxidants may improve and maintain a natural, healthy and glowing skin. Nourish the skin from within, using the right combination of nutrients, vitamins and minerals to support overall health of the immune system and skin. Vitamin C specifically contributes to normal collagen formation and wound healing. Vitamin A and E, support a healthy immune system, and Zinc plays a role in sebum production which is important in maintaining healthy skin.

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

Bovine Gelatine Capsule
Aerosil
Magnesium stearate
Potato starch

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 °C. Protect from moisture.

6.5 Nature and contents of container

PET container (175 mL) with a grey/silver Biogen PET lid.
Pack size: 30 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
www.biogen.co.za
Tel: 011 589 2322

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

This leaflet was last revised in November 2020.

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PATIENT INFORMATION LEAFLETSCHEDULING STATUS: **SO****BIOGEN RE I NU COLLAGEN & SKIN CAPSULES**

Each capsule contains:	%NRV*	%NVR*
Omega-3 Providing	300,00 mg	
EPA (Eicosapentaenoic acid)	15,00 mg	
DHA (Docosahexaenoic acid)	9,00 mg	
Hydrolysed Collagen	50,00 mg	
Vitamin C (Ascorbic acid)	50,00 mg	50 %
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Biotin (as D-Biotin)	50,00 µg	167 %

Preservatives in the capsule shell:

Methyl paraben 0,8 %.

Propyl paraben 0,2 %.

Sugar free.

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.

Read all of this leaflet carefully because it contains important information for you.

BIOGEN RE I NU COLLAGEN & SKIN is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN RE I NU COLLAGEN & SKIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN RE I NU COLLAGEN & SKIN with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What BIOGEN RE I NU COLLAGEN & SKIN is and what it is used for.
2. What you need to know before you take BIOGEN RE I NU COLLAGEN & SKIN.
3. How to take BIOGEN RE I NU COLLAGEN & SKIN.
4. Possible side effects.
5. How to store BIOGEN RE I NU COLLAGEN & SKIN.
6. Contents of the pack and other information.

1. WHAT BIOGEN RE I NU COLLAGEN & SKIN IS AND WHAT IT IS USED FOR

BIOGEN RE I NU COLLAGEN & SKIN is indicated as an Amino acid, Vitamin and Mineral complex for advanced skin health and nourishment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BIOGEN RE I NU COLLAGEN & SKIN

Do not take BIOGEN RE I NU COLLAGEN & SKIN:

- If you are hypersensitive (allergic) to any of the ingredients of BIOGEN RE I NU COLLAGEN & SKIN (listed in section 6).
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

- Taking multiple supplements and multivitamins may cause a cumulative intake of certain nutrients/substances. It is therefore recommended that a healthcare provider is consulted prior to use.
- If you suffer from any serious ailments or conditions; or if you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.
- Consult a health care provider before use if you take blood-thinning medicines, are asthmatic with sensitivity to aspirin, or for use beyond three months.
- Use should be avoided when taking immuno-suppressants, by patients with bleeding disorders, and by patients on 5-α-reductase inhibitors.
- Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

Other medicines and BIOGEN RE I NU COLLAGEN & SKIN

- Supplemental intake of certain ingredients may interfere with certain medicines and supplements, diseases and foods.
- If you are taking other medicines regularly, including complementary or traditional medicines, or start taking any additional medicines while taking this medicine, consult your healthcare provider for advice.
- Antibiotics: The concomitant use of zinc, as in BIOGEN RE I NU COLLAGEN & SKIN, with fluoroquinolones and tetracyclines reduces the absorption of these antibiotics. Advise patients to take these antibiotics 2 to 3 hours before or after taking BIOGEN RE I NU COLLAGEN & SKIN.
- Chelating agents: The use of zinc, as in BIOGEN RE I NU COLLAGEN & SKIN, with penicillamine reduces the absorption of penicillamine. Advise patients to separate doses by 2 to 3 hours.
- Phenylketonurics: It contains phenylalanine.
- Consult a healthcare practitioner before use if you have acidosis, atherosclerosis or methylene-tetra-hydrofolate reductase deficiency.
- Consult a healthcare practitioner before use if you have eosinophilia myalgia syndrome, liver disease or depression.

BIOGEN RE I NU COLLAGEN & SKIN with food and drink

BIOGEN RE I NU COLLAGEN & SKIN has no known interaction with food and drink.

Pregnancy, breastfeeding and fertility

Safety during pregnancy and breastfeeding has not been established. Do not use BIOGEN RE I NU COLLAGEN & SKIN while pregnant or breastfeeding.

Driving and using machinery

BIOGEN RE I NU COLLAGEN & SKIN is not likely to make you feel drowsy or sleepy. However, take special care before performing tasks that require your attention, until you know how you will react to BIOGEN RE I NU COLLAGEN & SKIN.

3. HOW TO TAKE BIOGEN RE I NU COLLAGEN & SKIN

Do not share your medicines with any other person.

Always take BIOGEN RE I NU COLLAGEN & SKIN exactly as indicated in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure. Do not exceed the recommended dosage and directions for use.

Adults: Take 1 capsule daily with food, or as recommended by a healthcare practitioner.

If you take more BIOGEN RE I NU COLLAGEN & SKIN than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you take more BIOGEN RE I NU COLLAGEN & SKIN than recommended it may cause increased risk of bleeding, gastrointestinal effects such as loose stools, nausea and vomiting, stomach cramps and pain, and tiredness.

If you forget to take BIOGEN RE I NU COLLAGEN & SKIN

If you have missed the dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take BIOGEN RE I NU COLLAGEN & SKIN at the next regularly scheduled time.

Do not take a double dose of BIOGEN RE I NU COLLAGEN & SKIN to make up for the forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

BIOGEN RE I NU COLLAGEN & SKIN may have side effects.

Not all side effects reported for BIOGEN RE I NU COLLAGEN & SKIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN RE I NU COLLAGEN & SKIN, please consult your healthcare provider for advice.

Tell your doctor as soon as possible if you notice any of the following side effects, which may occur less frequently:

- Skin reactions like rash, itching, sweating, hives, flushing, and edema.
- Skin sensitivity, eczema.
- Nausea (feeling sick), diarrhoea, stomach cramps, heartburn, digestive system effects.
- Fatigue.
- Headaches.

Tell your doctor as soon as possible if you notice any of the following side effects, of which the frequency is unknown;

- Chest pain, angina, flushing.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effectsIf you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIOGEN RE I NU COLLAGEN & SKIN.

5. HOW TO STORE BIOGEN RE I NU COLLAGEN & SKIN

- Store at or below 25 °C.
- Protect from moisture.
- Keep the capsules in the original container until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What BIOGEN RE I NU COLLAGEN & SKIN contains

The active substances are Omega-3 Fish oil, Hydrolysed Collagen, Vitamin C, Vitamin A, Zinc, Vitamin E, Astaxanthin, Copper, Biotin.

What BIOGEN RE I NU COLLAGEN & SKIN looks like and contents of the pack

Hard bovine gelatine capsule.

A white polypropylene securitainer with a white snap on cap containing a silica gel desiccant and 30 capsules.

HOLDER OF CERTIFICATE OF REGISTRATION

Biogen

23 Stag Road, Glen Austin, South Africa

info@biogen.co.za

www.biogen.co.za

Tel: 011 589 2322

THIS LEAFLET WAS LAST REVISED IN

October 2020.

REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLADSKEDULERINGSTATUS: **SO****BIOGEN RE I NU COLLAGEN & SKIN KAPSULES**

Elke kapsule bevat:	%NVR*	%NVR*	%NVR*
Omega-3 Verskaf	300,00 mg		300,00 mg
EPS (Eicosapentaenoïënsuur)	15,00 mg		15,00 mg
DHS (Dokosahexaenoïënsuur)	9,00 mg		9,00 mg
Gehidroliseerde Kollagen	50,00 mg		50,00 mg
Vitamien C (Askorbinsuur)	50,00 mg	50 %	50,00 mg
Vitamien A (as Vitamien A Asetaat)	10,00 mg (5 000 IU)	30 %	10,00 mg (5 000 IU)
Sink (as Sinksulfataat Heptahidraat)	10,00 mg		10,00 mg
Vitamien E (as Vitamien E Asetaat)	7,50 mg TE		7,50 mg TE
Astaksantien	4,00 mg	50 %	4,00 mg
Koper (as Koper AAC)	2 500,00 µg	278 %	2 500,00 µg
Biotin (as D-Biotin)	50,00 µg	167 %	50,00 µg

Preserveermiddels in die kapsule:

Metielparaben 0,8%.

Propylparaben 0,2%.

Suikervry.

KOMPLEMENTÈRE MEDISYNE: GESONDHEIDSAAVULLING

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Gesondheidsaavullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad aandaglik deur want dit bevat inligting wat belangrik is vir jou.

BIOGEN RE I NU COLLAGEN & SKIN is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet BIOGEN RE I NU COLLAGEN & SKIN niemendien steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie BIOGEN RE I NU COLLAGEN & SKIN met enige ander persoon deel nie.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is BIOGEN RE I NU COLLAGEN & SKIN en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy BIOGEN RE I NU COLLAGEN & SKIN neem.
3. Hoe om BIOGEN RE I NU COLLAGEN & SKIN te neem.
4. Moontlike newe-effekte.
5. Hoe om BIOGEN RE I NU COLLAGEN & SKIN te bêre.
6. Inhoud van die pak en ander inligting.

1. WAT IS BIOGEN RE I NU COLLAGEN & SKIN EN WAARVOOR WORD DIT GEBRUIK

BIOGEN RE I NU COLLAGEN & SKIN word aangedui as 'n aminosuur-, vitamien- en minerale kompleks vir gevorderde gesondheid en voeding van die vel.

2. WAT JY MOET WEET VOORDAT JY BIOGEN RE I NU COLLAGEN & SKIN**Moenie BIOGEN RE I NU COLLAGEN & SKIN neem nie:**

- Indien jy hipersensiteit (allergies) is vir enige van die bestanddele van BIOGEN RE I NU COLLAGEN & SKIN (gelys in afdeling 6).
- Indien jy swanger is of jou borsvoerd.

Waarskuwings en voorsorgmaatreëls

- Die neem van veulviedlike aanvullings en multivitamine kan 'n kumulatiewe inname van sekere voedingstowwe / stowwe veroorsaak. Dit word dus aanbeveel dat u 'n gesondheidsorgverskaffer raadpleeg voor gebruik.
- As u ernste kwalte van toestande het; of as u enige voorgeskrewe medikasie gebruik, moet u dit nagaan voordat u hierdie medisyne gebruik, by 'n gesondheidsorgverskaffer.
- Raadpleeg 'n gesondheidsorgverskaffer voordat u dit gebruik as u bloedverdunende medisyne gebruik, asmaties is en sensitief is vir aspirin, of vir gebruik langer as drie maande.
- Gebruik moet vermy word indien u op enige immunoonderdrukkers is, deur patiënt met behulp van meddingsversteurings en deur patiënt wat 5-α-reduksie-inhibiteerders ondergaan.
- Voedingsaanvullings moet nie 'n gebalanceerde dieet vervang nie. Moenie nie die aanbevolle dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

Ander medisyne en BIOGEN RE I NU COLLAGEN & SKIN

- Aanvullende inname van sekere bestanddele kan inmeng met sekere medisyne en aanvullings, siektes en voedsel.
- As u gereeld ander medisyne gebruik, insluit aanvullende of tradisionele medisyne, of as u enige medisyne begin gebruik raadpleeg ander gesondheidsorgverskaffer vir advies.
- Antibiotika: die gepaardgaande gebruik van sink, soos in BIOGEN RE I NU COLLAGEN & SKIN, met fluorokinolone en tetrasiklike verminder die opname van antibiotika. Pasiënt word aanbeveel om hierdie antibiotika 2 tot 3 uur te neem voor of na die neem van BIOGEN RE I NU COLLAGEN & SKIN.
- Chelaatverminders: die gebruik van sink, soos in BIOGEN RE I NU COLLAGEN & SKIN, met penisillamine verminder die opname van penisillamine. Pasiënt word aanbeveel om dosisse van 2 tot 3 uur te skei.
- Fenileketonurika: dit bevat fenylalanine.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik indien u asidose, aterosklerose het of metilleen-tetra-hidrofolaat of 'n reduksie-tekort.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as u eosinofilië-malgie-sindroom, lewerslike of depressie het.

BIOGEN RE I NU COLLAGEN & SKIN met kos en drank

BIOGEN RE I NU COLLAGEN & SKIN het geen bekende interaksie met kos of drinkgoed nie.

Swangerskap, borsvoerd en vrugbaardheid

Veiligheid tydens swangerskap en borsvoerd is nog nie vastgestel nie. Moenie BIOGEN RE I NU COLLAGEN & SKIN gebruik tydens swangerskap of borsvoerd nie.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat BIOGEN RE I NU COLLAGEN & SKIN jou lomerig of slaperig sal maak. Wees egter baie versigtig voordat jy take verryg wat konseptus verg, totdat jy weet hoe jy op BIOGEN RE I NU COLLAGEN & SKIN reageer.

3. HOE OM BIOGEN RE I NU COLLAGEN & SKIN TE NEEM

Moenie jou medisyne met enigemand anders deel nie.

Neem BIOGEN RE I NU COLLAGEN & SKIN altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker indien jy onseker is. Moenie meer neem as wat aangedui word nie.

Volwassenes: Neem 1 kapsule daagliks saam met kos, of soos aanbeveel deur 'n gesondheidsorgverskaffer.

Wat om te doen indien jy meer BIOGEN RE I NU COLLAGEN & SKIN geneem het as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy meer BIOGEN RE I NU COLLAGEN & SKIN neem as wat aanbeveel is, kan dit 'n verhoogde risiko vir bloeding, spysversterkingskanaal effekte soos los stoelgang, naerheid en braking, maagkrampe en -pyn, en moegheid veroorsaak.

Wat om te doen indien jy vergeet het om die omsoep te neem

Indien dit 'n paar uur later is, neem die dosis wat jy vergeslaan het sodra jy onthou. Indien dit byna tyd is vir jou volgende dosis, staan die dosis wat vergeet is oor en neem BIOGEN RE I NU COLLAGEN & SKIN op die gewone geskeduleerde tyd.

Moenie 'n dubbele dosis BIOGEN RE I NU COL