

**PROFESSIONAL INFORMATION**
**D 34.12 Multiple Substance Formulation. 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 JOINT CARE**
**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains

Glucosamine Sulphate (Shrimp) / Glukosamiensulfaat (Garnale)	375,00 mg
OptiMSM® [MSM (Methylsulfonylmethane)]	375,00 mg
Chondroitin Sulphate Sodium (Avian)	200,00 mg
Ascorbic acid (Vitamin C)	25,77 mg

Contains sugar, Isomalt (200 mg) per tablet.

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Tablet

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

BIOGEN JOINT CARE may help to relieve joint pain associated with osteoarthritis, protect against the deterioration of cartilage, and may support the maintenance of cartilage and joint health. OptiMSM® a sulphur containing compound for the maintenance of healthy joints, tendons, ligaments and other connective tissue.

**4.2 Posology and method of administration**
**Adults:**

Take two (2) tablets by mouth twice daily, preferably at meal times, or as recommended by your healthcare provider. Glucosamine is not indicated for the treatment of acute painful symptoms. Patients should seek medical advice if their symptoms deteriorate after commencing treatment with glucosamine.

**Patient with impaired renal and/or liver function:**

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

**Children and adolescents:**

Not recommended in children and adolescents below the age of 18 years (see section 4.4).

**4.3 Contraindications**

- If you have a hypersensitivity to the ingredients or any of the excipients listed in 6.1.
- Product should not be given to patients who are allergic to shellfish as the active ingredient is obtained from shellfish.

**4.4 Special warnings and precautions for use**

Special care should be taken with BIOGEN JOINT CARE.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- The presence of another joint disease and alternative treatment thereof should be excluded. Patients are advised to consult a healthcare provider if symptoms worsen.
- Exacerbation of asthma symptoms after initiation of glucosamine have been described. Therefore, asthmatic patients administering BIOGEN JOINT CARE should be aware of potential worsening of symptoms.
- No special studies were performed in patients with renal or hepatic insufficiency. The toxicological and pharmacokinetic profile of the product does not indicate limitations for these patients. However, administration to patients with severe hepatic or renal insufficiency should be under medical supervision.
- Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrose-isomaltase insufficiency should not take BIOGEN JOINT CARE.
- Caution is advised in treatment of patients with impaired glucose tolerance. Closer monitoring of blood sugar levels and where relevant insulin requirements may be necessary in diabetics at the beginning of treatment and periodically during treatment.
- The additive effect of concomitantly administered products containing Isomalt and dietary intake of Isomalt should be taken into account.
- Not suitable for children.
- Derived from seafood.
- Do not use together with Warfarin or other anticoagulant therapy.
- Not to be taken at bedtime.

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**

No specific drug interaction studies have been performed on BIOGEN JOINT CARE, however, the pharmacokinetic properties of Glucosamine Sulphate, OptiMSM®, Chondroitin Sulphate Sodium, and Ascorbic acid (Vitamin C).

**Interactions with Medicines**

- The concomitant use of glucosamine as in BIOGEN JOINT CARE and anticoagulants may affect blood coagulation and closer monitoring of the parameters may be considered in these patients when initiating or ending glucosamine.
- The concomitant use of glucosamine and chondroitin as in BIOGEN JOINT CARE and the use with warfarin can alter coagulation, patients on warfarin are recommended not to take glucosamine.
- Concomitant use of glucosamine as in BIOGEN JOINT CARE and tetracycline can increase the absorption and the tetracycline serum concentrations.
- Patients treated with oral vitamin K antagonists should be closely monitored at the time of initiation or termination of glucosamine therapy, due to possible interactions.
- Glucosamine may increase the bioavailability of paracetamol by reducing its metabolism and therefore reduce the therapeutic effects of the medicine.
- Clinical studies have indicated that glucosamine can increase the delivery of subcutaneous insulin.

**Interactions with Diseases/Impairments**

- BIOGEN JOINT CARE and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).

**Interactions with Foods**

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN JOINT CARE.

**4.6 Fertility, pregnancy and lactation**

The safety and efficacy of BIOGEN JOINT CARE in 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 machines have been performed. If dizziness or drowsiness is experienced, car driving and the operating of machinery is not recommended.

**4.8 Undesirable effects**

Orally, Glucosamine Sulphate, OptiMSM®, Chondroitin Sulphate Sodium, and Ascorbic acid (Vitamin C) is well-tolerated.

**Summary of adverse reactions**

Gastrointestinal disorders:

*Frequent:* Nausea, abdominal pain, indigestion and/ or digestive disorders, constipation and diarrhoea.  
*Frequency unknown:* Hypercholestelelaemia, epigastralgia.

Nervous system disorders:

*Frequency unknown:* Headache and fatigue.

Skin and subcutaneous tissue disorders:

*Infrequent:* Rash, itch and blushing.  
*Unknown frequency:* Urticaria, eczema and pruritus.

**Description of selected adverse reactions**

BIOGEN JOINT CARE may cause several adverse reactions, such as gastrointestinal disturbances, such as nausea, abdominal pain, digestive disorders, constipation and diarrhoea.

**Paediatric Population**

Glucosamine is not recommended for use by children under 18 years, as insufficient data are available concerning its safety and efficacy.

**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. Health care 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**

See section 4.8.

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

**5. PHARMACOLOGICAL PROPERTIES**

BIOGEN JOINT CARE, may help to relieve joint pain associated with osteoarthritis, protect against the deterioration of cartilage, and may support the maintenance of cartilage and joint health. OptiMSM® a Sulphur containing compound for the maintenance of healthy joints, tendons, ligaments and other connective tissue.

**5.1 Pharmacodynamic properties**

Mechanism of action:

*Glucosamine Sulphate (Shrimp)*; Non-steroidal anti-inflammatory and antirheumatic drug. Glucosamine is an endogenous substance, a common component of the polysaccharide chains in the cartilaginous matrix and the glycosaminoglycans in the synovial fluid. In *in-vitro* and *in-vivo* studies have revealed that glucosamine stimulates the synthesis of physiological glucosaminoglycans and proteoglycans by the chondrocytes from the hyaluronic acid by synoviocytes stimulate production of cartilage components and allow rebuilding of damaged cartilage.

*OptiMSM® [MSM (Methylsulfonylmethane)]*; functions as a sulfur metabolism modifier, promoting the apparent retention of sulfur and rapidly altering sulfur metabolism in the body to maintain normal connective tissues.

*Chondroitin Sulphate Sodium (Avian)* Chondroitin sulfate functions as a major component of the cartilage, which joins a central protein, forming what is called proteoglycan, an intricate extracellular matrix. It is proposed that chondroitin sulfate supply can provide new building blocks for the synthesis of new matrix components. The therapeutic effect of chondroitin sulfate in patients suffering from arthritis, is due to an anti-inflammatory activity at the level of the cellular components of the inflammation (*in vivo*), to the stimulation of the synthesis of endogen proteoglycans (*in vitro*) and hyaluronic acid (*in vivo*), and to a decrease in the catabolic activity of chondrocytes (*in vivo*), inhibiting some proteolytic enzymes (collagenase, elastase, proteoglycanase, phospholipase A2, N-acetylglucosaminidase, etc.) (*in vitro, in vivo*) and the formation of other substances that damage the cartilage (*in vitro*).

*Ascorbic acid (Vitamin C)*: required for collagen formation and tissue repair.

**Pharmacodynamic effects:**

*Glucosamine Sulphate (Shrimp)* Glucosamine was found not to bind to plasma proteins and up to 43 to 47 % was associated with blood cells.

*OptiMSM® [MSM (Methylsulfonylmethane)]* Blood serum MSM levels displayed the rise and fall pattern consistent with rapid absorption within an hour, followed by slower elimination from the bloodstream over the course of one or two days.

*Chondroitin Sulphate Sodium (Avian)*, in clinical trials, chondroitin sulfate has been reported a significant pain relief. One of the characteristics of chondroitin is a slow onset of action with a maximal effect attained after several months. Chondroitin sulfate treatment improves symptoms such as pain and functional impotence, or causes such symptoms to disappear altogether. Movement in the affected joints is improved. The effects of chondroitin sulfate treatment are sustained, lasting 2 to 3 months after treatment has stopped.

*Ascorbic acid (Vitamin C)*: Normal plasma concentrations of ascorbic acid are about 10 to 20 µg/mL. Total body stores of ascorbic acid have been estimated to be about 1.5 g with about a 30 to 45 mg daily turnover. Plasma concentrations of ascorbic acid rise as the dose ingested is increased until a plateau is reached with doses of about

90 to 150 mg daily.

**5.2 Pharmacokinetic properties**

Absorption:

*Glucosamine Sulphate (Shrimp)*; oral intake, glucosamine sulphate salt is completely ionised in the acidic environment of the stomach, as a result of which free glucosamine becomes available for absorption in the small intestine. About 80 % is absorbed, but as a consequence of the first-pass metabolism in the liver the bioavailability is significantly lower; the exact percentage is not known.

*OptiMSM® [MSM (Methylsulfonylmethane)]*; Absorption of MSM by the small intestine and accumulation of the associated sulphur moiety in selected tissues.

*Chondroitin Sulphate Sodium (Avian)*, is absorbed from the gastrointestinal tract. The bioavailability of chondroitin sulfate ranges from 10-20 % following oral administration. Reports have shown a consistent accumulation of the compound in joint tissue. The steady-state is attained after 3-4 days and it takes around 3-6 months to obtain the maximal effect.

*Ascorbic acid (Vitamin C)* ascorbic acid is readily absorbed after oral administration but the proportion does decrease with the dose. GI absorption of ascorbic acid may be reduced in patients with diarrhoea or GI diseases.

No clinical data are available on the effects of BIOGEN JOINT CARE.

Distribution:

*Glucosamine Sulphate (Shrimp)* after oral absorption, glucosamine is significantly distributed in extra-vascular compartments including synovial fluid with an apparent distribution volume 37-fold higher than the total body water in humans. Glucosamine does not bind to plasma proteins. It is therefore highly unlikely that glucosamine might produce displacement drug interaction when co-administered with other drugs that are highly bound to plasma proteins.

*OptiMSM® [MSM (Methylsulfonylmethane)]*; MSM taken orally appeared to be widely distributed and has been detected in brain, cerebrospinal fluid, serum or plasma. MSM crosses the blood-brainbarrier and is distributed in all brain parts.

Chondroitin Sulphate Sodium (Avian), when administered orally, the apparent volume of distribution changed to 0.44ml/g.

*Ascorbic acid (Vitamin C)*, becomes widely distributed in body tissues with large concentrations found in the liver, leukocytes, platelets, glandular tissues, and the lens of the eye. In the plasma about 25 % of the ascorbic acid is bound to proteins.

Metabolism:

*Glucosamine Sulphate (Shrimp)*, is dissociated in the acidic milieu of the stomach, resulting in the release of glucosamine itself. The glucosamine is used in the joint cartilage and the cartilage cells for the production of glycosaminoglycans.

*OptiMSM® [MSM (Methylsulfonylmethane)]*, taken orally is rapidly absorbed within an hour, and serum MSM levels are dose and time-dependent.

*Chondroitin Sulphate Sodium (Avian)*, is not metabolized by cytochrome P450. Reports have indicated the presence in plasma of mono-, oligo- and polysaccharides with a molecular weight of less of 5 kDa which are derived from the partial digestion of exogenous chondroitin sulfate.

*Ascorbic acid (Vitamin C)* Ascorbic acid is reversibly oxidised to dehydroascorbic acid in the body. This reaction, which proceeds by removal of the hydrogen from the enediol group of ascorbic acid, is part of the hydrogen transfer system. The two forms found in body fluids are physiologically active. Some ascorbic acid is metabolised to inactive compounds including ascorbic acid-2-sulfate and oxalic acid.

Excretion:

*Glucosamine Sulphate (Shrimp)*, the elimination half-life was estimated at 15 hours, on the basis of a single oral daily dose and excreted in the urine.

*OptiMSM® [MSM (Methylsulfonylmethane)]*, the estimated elimination time was around 8 hours.

*Chondroitin Sulphate Sodium (Avian)*, is excreted in the urine as intact polymers and as partial degradation product. The approximate half-life of chondroitin sulfate and its derivative metabolites is 15 hours.

*Ascorbic acid (Vitamin C)* when the body is saturated with ascorbic acid and blood concentrations exceed the threshold, unchanged ascorbic acid is excreted in the urine. When tissue saturation and blood concentrations of ascorbic acid are low, administration of the vitamin results in little or no urinary excretion of ascorbic acid. Inactive metabolites of ascorbic acid such as ascorbic acid-2-sulfate and oxalic acid are excreted in the urine.

**Preclinical safety data**

When used orally and appropriately, Glucosamine Sulphate, OptiMSM®, Chondroitin Sulphate Sodium, and Ascorbic acid (Vitamin C) is recognized as possibly safe.

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

Magnesium stearate and Isomalt DC101.

**6.2 Shelf Life**

24 Months.

**6.3 Special precautions for storage**

Store in a cool, dry place at or below 25 °C. Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

**6.5 Nature and contents**

60/120 White oval tablets

The container is a 250 mL/ 300 mL PET container. The cap is a white plastic cap with a tamper evident seal.

**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: 0860 347243

**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_Joint Care 60-120s	<b>SIZE:</b> 210mm x 393mm
<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>COLOURS:</b>	<b>FINISHING:</b>
<input checked="" type="checkbox"/> K <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss
<input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<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.	

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S0

**PRODUCT NAME**  
**BIOGEN JOINT CARE**

Each tablet contains:  
Glucosamine Sulphate (Shrimp), OptiMSM® [MSM (Methylsulfonylmethane)], Chondroitin Sulphate Sodium (Avian), and Ascorbic acid (Vitamin C).  
Contains sugar, Isomalt (200 mg) per tablet.

**D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.**  
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

**Read all of this leaflet carefully because it contains important information for you.**  
BIOGEN JOINT CARE is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN JOINT CARE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN JOINT CARE 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 JOINT CARE is and what it is used for.
2. What you need to know before you take BIOGEN JOINT CARE.
3. How to take BIOGEN JOINT CARE.
4. Possible side effects.
5. How to store BIOGEN JOINT CARE.
6. Contents of the pack and other information.

**1. What BIOGEN JOINT CARE is and what it is used for**  
BIOGEN JOINT CARE may help to relieve joint pain associated with osteoarthritis, protect against the deterioration of cartilage, and may support the maintenance of cartilage and joint health. OptiMSM® a sulphur containing compound for the maintenance of healthy joints, tendons, ligaments and other connective tissue.

**2. What you need to know before you take BIOGEN JOINT CARE**  
**Do not take BIOGEN JOINT CARE:**

- If you have a hypersensitive (allergic) to any of the ingredients listed (see section 6).
- If you are hypersensitive to shellfish.
- If you are hypersensitive to sulphur.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BIOGEN JOINT CARE.

**Warnings and precautions**  
Special care should be taken with BIOGEN JOINT CARE.  
If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Alternative treatment of another joint disease should be excluded.
- An increase of asthma symptoms after starting with glucosamine supplementation can be expected. It is therefore advised that if you are asthmatic, you should be aware of potential worsening of symptoms when using BIOGEN JOINT CARE.
- Caution is advised if you have impaired glucose tolerance. Closer monitoring of blood sugar levels and where relevant insulin requirements may be necessary in diabetics at the beginning of treatment and periodically during treatment.
- Caution is advised if you suffer from severe hepatic or renal insufficiency, supplementation with BIOGEN JOINT CARE should be under medical supervision.
- The additive effect of products containing Isomalt and dietary intake of Isomalt should be taken into account.
- Derived from seafood.
- Do not use together with Warfarin or other anticoagulant therapy
- Not to be taken at bedtime.

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

**Children and adolescents**  
BIOGEN JOINT CARE is not recommended for use in children under the age of 18 years.

**Other medicines and BIOGEN JOINT CARE**  
Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine.

It is advised to consult your doctor if you want to take BIOGEN JOINT CARE combined with other medicines or treatments such as:

- BIOGEN JOINT CARE may interact with Warfarin or other anticoagulants.
- Tetracycline as it may cause interactions.
- Vitamin K antagonists as it may affect Vitamin K levels and have additive effects or may reduce therapeutic effects of the medicine.
- Glucosamine may increase the bioavailability of paracetamol therefore reduce the therapeutic effects of the medicine.
- Glucosamine can increase insulin levels.

**Interactions with Diseases / Impairments**  
It is advised that the use of BIOGEN JOINT CARE should be discontinued at least 2 weeks before elective surgical procedures (see section 4).

**Interactions with Foods**  
Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN JOINT CARE.

**Pregnancy, breastfeeding and fertility**  
The safety and efficacy of BIOGEN JOINT CARE in pregnancy and lactation has not been established.

**Driving and using machinery**  
Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN JOINT CARE does not affect their performance.

**3. How to take BIOGEN JOINT CARE**  
Do not share your medicines with any other person.

Always take BIOGEN JOINT CARE exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adults:**  
Take two (2) tablets by mouth twice daily, preferably at meal times, or as recommended by your healthcare provider. Glucosamine is not indicated for the treatment of acute painful symptoms. Patients should seek medical advice if their symptoms deteriorate after commencing treatment with glucosamine.

**Elders:**  
No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

**Patient with impaired renal and/or liver function:**  
In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4).

**Children and adolescents:**  
Not recommended in children and adolescents below the age of 18 years (see section 4).

The safety and efficacy of BIOGEN JOINT CARE in children has not yet been established. Not allowed in children under 18 years.

**If you take more BIOGEN JOINT CARE than you should**  
No known information. In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN JOINT CARE with you so the doctor will know what you have taken.

**If you forget to take BIOGEN JOINT CARE**  
Do not take a double dose to make up for forgotten individual doses.

**4. Possible side effects**  
BIOGEN JOINT CARE can have side effects.  
Not all side effects reported for BIOGEN JOINT CARE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN JOINT CARE, please consult your healthcare provider for advice.

Side effects associated:  
**Frequent:** Nausea, abdominal pain, indigestion and/or digestive disorders, constipation and diarrhoea.  
**Frequency unknown:** Hypercholestealaemia, epigastralgia, Headache and fatigue, Urticaria, eczema and pruritus.  
**Infrequent:** Rash, itch and blushing.

Should your general health worsen or if you experience any untoward effects while BIOGEN JOINT CARE, please consult your doctor, pharmacist or other healthcare practitioner for advice.

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

**Reporting of side effects**  
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the 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 JOINT CARE.

**5. How to store BIOGEN JOINT CARE**

- Store at or below 25 °C.
- Protect from light and moisture.
- 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 JOINT CARE contains**

**What BIOGEN JOINT CARE contains**  
Active ingredients per tablet Glucosamine Sulphate (Shrimp) 375.00 mg, OptiMSM® [MSM (Methylsulfonylmethane)] 375.00 mg, Chondroitin Sulphate Sodium (Avian) 200.00 mg, and Ascorbic acid (Vitamin C) 25.77 mg.  
Contains sugar, Isomalt (200 mg) per tablet.  
The other ingredients are magnesium stearate and isomalt DC101.

**What BIOGEN JOINT CARE looks like and contents of the pack**  
PET container with a Biogen lid. Packed in a unit carton.  
BIOGEN JOINT CARE is a white, oval tablet.

**Holder of certificate of registration**  
Biogen  
23 Stag Road, Glen Austin, South Africa  
info@biogen.co.za  
www.biogen.co.za  
Tel: 0860 347243

**This leaflet was last revised in**  
November 2021.

**Registration Number**  
Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD**

**SKEDULERINGSTATUS:** S0

**PRODUKNAAM**  
**BIOGEN JOINT CARE**

Elke tablet bevat:  
Glukosamiensulfaat (Garnale), OptiMSM® [MSM (Methylsulfonylmethane)], Chondroitin Sulphate Natrium (Avian), en askorbiensuur (Vitamiën C).  
Bevat suiker, Isomalt (200 mg) per tablet.

**D 34.12 Meervoudige Bestanddeel Formulasie. Komplementêre Medisyne. Gesondheidsaanvulling.**  
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

**Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir u.**  
BIOGEN JOINT CARE is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN JOINT CARE nietermin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN JOINT CARE met enigiemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of aptekek indien u verdere inligting of advies nodig het.

**Wat is in hierdie inligtingsblad**

1. Wat is BIOGEN JOINT CARE en waarvoor word dit gebruik.
2. Wat u moet weet voordat u BIOGEN JOINT CARE neem.
3. Hoe om BIOGEN JOINT CARE te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BIOGEN JOINT CARE te bêre.
6. Inhoud van die verpakking en ander inligting.

**1. Wat is BIOGEN JOINT CARE en waarvoor word dit gebruik**  
BIOGEN JOINT CARE kan help om gewrigspyn te verlig geassosieer met osteoartritis, te beskerm teen die agteruitgang van kraakbeen, en kan die handhawing van kraakbeen en gewrigsgesondheid ondersteun. OptiMSM® 'n swaelbevattende verbinding vir die instandhouding van gesonde gewrigte, tendons, ligamente en ander bindweefsel.

**2. Wat u moet weet voordat u BIOGEN JOINT CARE neem**  
**Moenie BIOGEN JOINT CARE neem nie:**

- Indien u hipersensitief (allergies) is vir enige van die ander bestanddele gelys (sien afdeling 6).
- Indien u hipersensitief is vir skulpvis.
- Indien u hipersensitief is vir swaet.
- Indien u dokter vir u gesê het dat u 'n onverdraagsaamheid teenoor sekere suikers het, kontak u dokter voordat u BIOGEN JOINT CARE gebruik.

**Waarskuwings en voorsorgmaatreëls**  
Spesiale sorg moet toegepas word met die gebruik van BIOGEN JOINT CARE.  
Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik. Let asseblief op die volgende:

- Alternatiewe behandeling van 'n ander gewrigsiekte moet uitgesluit word.
- 'n Toename in asma-simptome na die aanvang van glukosamiëaanvulling kan ver wag word. Dit word dus aangeraai dat as u asma-ties is, u bewus moet wees van moontlike verergering van simptome wanneer u BIOGEN JOINT CARE gebruik.
- Omsigtigheid word aangeraai as u verswakte glukosetoleransie het. Nouer monitering van bloedsuikervlakke en waar toepaslik insulienbehoefes kan nodig wees by diabeete aan die begin van behandeling en periodiek tydens behandeling.
- Omsigtigheid word aangeraai indien u aan ernstige lever- of nierinsufficiëntie ly, aanvulling met BIOGEN JOINT CARE moet onder mediese toesig wees.
- Die bykomende effek van produkte wat Isomalt bevat en dieetinnam van Isomalt moet in ag geneem word.
- Afkomstig van seekos.
- Moet nie saam met Warfarin of ander antikoagulanterapie gebruik nie
- Moet nie voor slaaptyd geneem word nie.

Voedingsaanvullings moet nie 'n gebalanseerde dieet vervang nie. Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

**Kinders en adolessente**  
BIOGEN JOINT CARE word nie vir kinders onder die ouderdom van 18 jaar aanbeveel nie.

**Ander medisyne en BIOGEN JOINT CARE**  
Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN JOINT CARE wil kombineer saam met ander medisyne of behandelinge soos:

- BIOGEN JOINT CARE kan interaksie hê met Warfarin of ander antikoagulanterapie.
- Tetrasiklieke aangesien dit interaksies kan veroorsaak.
- Vitamiën K-antagoniste aangesien dit Vitamiën K-vlakke kan beïnvloed en bykomende effekte kan hê of terapeutiese effekte van die medisyne kan verminder.
- Glukosamien kan die biobeskikbaarheid van parasetamol verhoog en verminder dus die terapeutiese effekte van die medisyne.
- Glukosamien kan insulienvlakke verhoog.

**Interaksies met siektes / gestremdhede**  
Dit word aanbeveel dat die gebruik van BIOGEN JOINT CARE ten minste 2 weke voor elektiewe chirurgiese prosedures gestaak moet word (sien afdeling 4).

**Interaksies met voedsel**  
Vitamiene, minerale en voedingsstowwe wat van ander bronne verkry word, moet in ag geneem word wanneer BIOGEN JOINT CARE voorgeskryf / voorgestel word.

**Swangerskap, borsvoeding en vrugbaarheid**  
Die veiligheid en doeltreffendheid van BIOGEN JOINT CARE tydens swangerskap en laktasie is nie vasgestel nie.

**Bestuur en gebruik van masjinerie**  
Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik totdat hulle redelik seker is dat BIOGEN JOINT CARE nie hul werkverrigting beïnvloed nie.

**3. Hoe om BIOGEN JOINT CARE te neem**  
Moenie u medisyne met enigiemand anders deel nie.

Neem, BIOGEN JOINT CARE altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat u dokter of aptekek vir u aanbeveel het. Vra gerus u dokter of aptekek indien u onseker is.

**Volwassenes:**  
Neem twee (2) tablette twee keer per dag per mond, verkieslik tydens maaltye, of soos aanbeveel deur jou gesondheidsorgverskaffer.  
Glucosamine is nie aangedui vir die behandeling van akute pynlike simptome nie. Pasiënte moet mediese advies inwin indien hul simptome versleg nadat behandeling met glukosamien begin is

**Bejaardes:**  
Geen spesifieke studies is by ouer pasiënte uitgevoer nie, maar volgens kliniese ervaring is dosisaanpassing nie nodig wanneer andersins gesonde, ouer pasiënte behandel word nie.

**Pasiënt met verswakte nier- en/of leverfunksie:**  
By pasiënte met verswakte nier- en/of leverfunksie kan geen dosisaanbevelings gegee word nie, aangesien geen studies uitgevoer is nie (sien ook afdeling 4).

**Kinders en adolessente:**  
Word nie aanbeveel by kinders en adolessente onder die ouderdom van 18 jaar nie (sien afdeling 4).

Die veiligheid en doeltreffendheid van BIOGEN JOINT CARE by kinders is nog nie vasgestel nie. Nie toegelaat by kinders onder 18 jaar nie.

**Wat om te doen indien u meer BIOGEN JOINT CARE geneem het as wat u moet**  
Geen bekende informasie. Indien u meer BIOGEN JOINT CARE geneem het as wat u moes, of in die geval van 'n oordosis, raadpleeg u dokter of aptekek. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.  
Neem hierdie inligtingsblad en die oorblywende BIOGEN JOINT CARE olie saam sodat die dokter kan sien wat u ingeneem het.

**Indien u vergeet om BIOGEN JOINT CARE te neem**  
Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

**4. Moontlike nuwe-effekte**  
BIOGEN JOINT CARE kan nuwe-effekte hê.  
Nie alle nuwe-effekte wat aangemeld is vir BIOGEN JOINT CARE is in hierdie voulibjet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN JOINT CARE, raadpleeg u gesondheidsorgwerker vir advies.

Nuwe-effekte geassosieer:  
**Algemeen:** Naarheid, buikpyn, spysvertering en/of spysverteringstoornisse, hardlywigheid en diarree.  
**Frekvensie onbekend:** Hipercholestelemie, epigastralgie, Hoofpyn en moegheid, Urtikaria, ekseem en pruritus.  
**Ongereeld:** Uitslag, jeuk en bloos.

Raadpleeg u dokter, aptekek of ander gene -esheer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN JOINT CARE neem.

As u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet u dokter of aptekek daarvan in kennis gestel word.

**Rapportering van nuwe-effekte**  
Indien u nuwe-effekte ondervind, bespreek dit met u dokter of aptekek. U kan ook nuwe-effekte aan SAHPRA rapporteer via die Adverse Drug Reactions Reporting Form, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.  
Deur nuwe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN JOINT CARE te verskaf.

**5. Hoe om BIOGEN JOINT CARE te bêre**

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.
- Neem alle ongebruikte medisyne terug na u aptekek.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

**6. Inhoud van die pak en ander inligting**

**Wat BIOGEN JOINT CARE bevat**  
Aktiewe bestanddele per tablet, Glukosamiensulfaat (Garnale) 375.00 mg, OptiMSM® [MSM (Methylsulfonylmethane)] 375.00 mg, Chondroitin Sulphate Natrium (Avian) 200.00 mg, en askorbiensuur (Vitamiën C) 25.77 mg.  
Bevat suiker, Isomalt (200 mg) per tablet.  
Die ander bestanddele is magnesiumsteraat en Isomalt DC101.

**Hoe BIOGEN JOINT CARE lyk en inhoud van die verpakking**  
PET container with a Biogen lid. Packed in a unit carton.  
BIOGEN JOINT CARE is 'n wit, ovaal tablet.

**Houer van die registrasiesertifikaat**  
Biogen  
Stagweg 23, Glen Austin, Suid Afrika  
info@biogen.co.za  
www.biogen.co.za  
Tel: 0860 347243

**Hierdie inligtingsblad is laas hersien in**  
November 2021.

**REGISTRASIONOMMER**  
Sal met registrasie deur SAHPRA toegeken word.

<b>JOB:</b> BPS_Joint Care 60-120s		<b>SIZE:</b> 210mm x 393mm	
<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>COLOURS:</b>		<b>FINISHING:</b>	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Spot UV	<input type="checkbox"/> Matte	<input type="checkbox"/> Gloss	<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.			