

BIOGEN GLUCOSAMINE CHONDROITIN

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: SO

1. NAME OF THE MEDICINE

BIOGEN GLUCOSAMINE CHONDROITIN (Tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each BIOGEN GLUCOSAMINE CHONDROITIN tablet contains:

Glucosamine Sulphate (Marine) 500 00 mg Methylsulfonylmethane (MSM) 250,00 mg 200.00 ma Chondroitin Sulphate (Bovine)

Contains sugar; mannitol (0.14 g) and sorbitol (0.37 g) per tablet For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN GLUCOSAMINE CHONDROITIN for joint health, may help to relieve joint pain, protect against the deterioration of cartilage, and may support the maintenance of cartilage and joint health

4.2 Posology and method of administration

Adults 18 years and older:

Take 1 (one) tablet three times daily, or as recommended by a healthcare provider Do not take at bedtime. Use for a minimum of one month to see beneficial effects.

BIOGEN GLUCOSAMINE CHONDROITIN is not recommended for individuals below the age of 18 years.

4.3 Contraindications

- If you have a hypersensitivity to any of the ingredients or the excipients listed in 6.1.
- Hypersensitivity to shellfish or sulphur.
- If you are taking warfarin or other anticoagulant medications.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN GLUCOSAMINE CHONDROITIN

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

- Consult a relevant healthcare provider prior to use if you are pregnant or breastfeeding.
- . Consult a relevant healthcare provider prior to use if you have asthma.
- Consult a health care provider prior to use if you have liver or gall bladder diseases, and/or intestinal obstruction.
- Consult a healthcare provider if symptoms persist or worsen.

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 with Medicines

- Topoisomerase II Inhibitors: glucosamine may induce resistance to topoisomerase II inhibitors.
- . Anticoagulants: Glucosamine might increase the anticoagulant effects of warfarin and increase the risk of bruising and bleeding

JOB: BPS_GLUCOSAMINE CHONDROITIN (60's/120's)	SIZE: 310mm x 165mm
STOCK: Foil Substrate: Clear Substrate: White Substrate: Paper: X Other: Clear Substrate: Other: Other	
COLOURS:	FINISHING:
К	Foil / Holographic Foil Matte Gloss
	Spot UV Doming Embossing
PLEASE CHECK CAREFILLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once	

Interactions with Diseases / Impairments

- Asthma: Glucosamine might exacerbate asthma. The mechanism of this allergic risk is unknown. Use cautiously in patients with asthma
- . Glaucoma: There is some concern that taking glucosamine sulphate might increase intraocular pressure in
- Shellfish Alleray: There is concern that glucosamine products might cause allergic reactions in people who are sensitive to shellfish. Glucosamine is derived from the exoskeletons of shrimp, lobster, and crabs,

Interactions with Foods

· Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN GLUCOSAMINE CHONDROITIN

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established (see section 4.3)

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 BIOGEN GLUCOSAMINE CHONDROITIN does not adversely affect their performance.

4.8 Undesirable effects

Orally, BIOGEN GLUCOSAMINE CHONDROITIN is well-tolerated.

4.8 a Summary of adverse reactions

BIOGEN GLUCOSAMINE CHONDROITIN can have side effects

4.8 b Most common adverse effects

Orally: Bloating, constipation, cramps, diarrhea, heartburn, nausea.

Hypersensitivity: Unknown frequency: Allergic reactions.

Gastrointestinal complaints: Unknown frequency; gastrointestinal problems, including epigastric and abdominal pain, cramps, heartburn, diarrhea, nausea, dyspepsia, vomiting, constipation, and flatulence

Immunologic: Unknown frequency: There is some concern that glucosamine products might cause allergic reactions in sensitive individuals.

Neurologic: Unknown frequency: drowsiness and headache.

Other: Unknown frequency: glucosamine might increase the risk of metabolic disturbances resulting in increased cholesterol levels and blood pressure

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

4.8 c Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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

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

Mechanism of action:

Glucosamine sulphate: Glucosamine is required for the synthesis of glycoproteins, glycolipids, and glycosaminoglycans (also known as mucopolysaccharides). These carbohydrate-containing compounds are found in tendons, ligaments, cartilage, synovial fluid, mucous membranes, structures in the eye, blood vessels, and heart valves.

Methylsulfonylmethane (MSM): MSM is a naturally occurring compound that is a metabolite of dimethylsulfoxide. MSM is primarily used for osteoarthritis. Research suggests MSM might inhibit degenerative changes in joints in animal models of osteoarthritis

Chondroitin sulphate: chondroitin sulphate protects cartilage against degradation by inhibiting the action of the enzymes leukocyte elastase and hyaluronidase or increasing hyaluronan synthases, by decreasing the migration of polymorphonuclear leukocytes, and by increasing the synthesis of collagen, proteoglycans, and hyaluronic acid.

5.2 Pharmacokinetic properties

Glucosamine sulphate

Absorption: Glucosamine is absorbed from the small intestine.

Distribution: Glucosamine is incorporated into plasma proteins during first-pass metabolism, and unbound glucosamine is concentrated in the articular cartilage.

Metabolism: Glucosamine sulphate is extensively metabolized in the liver.

Excretion: Glucosamine is thought to be excreted mainly in the urine.

Methylsulfonylmethane (MSM):

Distribution: Supplemental MSM crosses the blood-brain barrier.

Excretion: In animal research, giving DMSO resulted in MSM excretion in the urine, but not the feces.

Chondroitin sulphate:

Absorption: oral absorption of chondroitin sulphate is relatively fast, but oral bioavailability is moderate (12 % to 24

Distribution: oral intake of chondroitin sulphate results in its depolymerization and degradation, but after time, it may accumulate in target joints

Metabolism: the plasma levels of exogenous chondroitin sulphate decreased according to a two-compartmental

Excretion: Urinary excretion as high- and low-molecular-weight breakdown products is the main route of elimination

6. PHARMACFUTICAL PARTICULARS

6.1 List of excipients

· Polyvinylpyrrolidone, mannitol, sorbitol, magnesium stearate, white film-coating, purified water.

6.2 Incompatibilities

No compatibility studies have been performed: BIOGEN GLUCOSAMINE CHONDROITIN must not be mixed with other medications.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

- . Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN
- . Do not use after the expiry date stated on the label.
- Return all unused BIOGEN GLUCOSAMINE CHONDROITIN to your pharmacist
- . Do not dispose of unused BIOGEN GLUCOSAMINE CHONDROITIN in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents of container

60 / 120 Large, white-coated tablets are available in a white 250 ml / 300 ml PET container sealed with a white plastic screw can

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen

23 Stag Road Glen Austin South Africa Tel: 0860 347 243

Email: info@biogen.co.za Website: www biogen co za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

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