Biofizz Glucosamine 1500mg Powder_Leaflet

10cm (H) x 16cm (W)

BIOFIZZ GLUCOSAMINE 1500MG POWDER

Composition: Each sachet contains:
Glucosamine Sulphate Sodium Chloride 1884mg
(equivalent to Glucosamine Sulphate 1500mg)

Derived from Seafood

Product Description: White or almost white crystalline powder is filled in aluminium sachet. The solution is clear and colourless with salty taste after dissolved the powder in water.

Indication: Adjuvant therapy for osteoarthritis.

Recommended Dose: Adult: One sachet to be taken once a day. The entire contents of one sachet should be fully dissolved in at least 250 ml of water (one glass) and drink immediately.

Pharmacodynamics:

Glucosamine
Glucosamine which can stimulate the production of cartilage-building compounds, restore damaged cells of cartilage tissue and has some anti-inflammatory abilities.

Pharmacokinetics:

Glucosamine

Absorption

After oral administration, bioavailability is low due to first-pass hepatic metabolism 26%. The gastrointestinal absorption is close to 90%.

Distribution

Glucosamine is not protein-bound, but rather incorporates into plasma proteins (primarily globulins) Volume of distribution: 2.5 Liters.

Metabolism

- Liver extensive
The first-pass effect in the liver in which more than 70% of glucosamine is metabolized.

Excretion

Renal Excretion, 10% Feces, 11%
Part of a dose of glucosamine sulfate is eliminated as carbon dioxide via expired air.

Contraindication:

It is contraindicated in patient with hypersensitivity to glucosamine sulphate. As the active ingredient is obtained from seafood, the product should not be given to patients who are allergic to seafood.

Warning and Precaution:

A doctor must be consulted if this medicine is intended for long term use.

A doctor must be consulted to rule out the presence of joint diseases for which other treatment should be considered.

As the risk of diabetogenic effects is unknown and until further evidence becomes available, caution should be exercised in patients with diabetes or a predisposition for diabetes.

Therefore, in patients with impaired glucose tolerance, pre-diabetics and diagnosed diabetics (Type I and II), monitoring of the blood glucose levels should be increased, as deemed necessary, before start of treatment, periodically during treatment and at the end of the treatment, as determined by the primary Healthcare Professional.

Where relevant, monitoring of insulin requirements is also recommended before start of treatment, periodically during treatment and at the end of the treatment under medical supervision.

In patients with a known risk factor for cardiovascular disease, monitoring of the blood lipid levels is recommended during treatment with Glucosamine sulphate since hypercholesterolemia has been observed in a few patients treated with glucosamine. The results should be a factor in determining whether treatment is continued after 2-3 months.

A report on exacerbated asthma symptoms triggered after initiation of glucosamine therapy has been described (symptoms resolved after withdrawal of glucosamine). Asthmatic patients starting on glucosamine should therefore be aware of potential worsening of symptoms.

Effects on Ability to Drive and Use Machines:
Not known

Interactions with Other Medicaments:

Hypoglycaemic agents

Close monitoring of blood sugar level is recommended for diabetics on hypoglycaemic agents.

Warfarin
There are limited data on possible drug interactions with glucosamine, but increments in the INR parameter have been reported with oral vitamin K antagonists. Patients treated with oral vitamin K antagonists should therefore be closely monitored at the time of initiation or termination of glucosamine therapy.

Tetracyclines
Concurrent treatment with glucosamine may increase the absorption and serum concentration of tetracyclines, but the clinical relevance of this interaction is probably limited. If the patient is taking oral tetracycline, they should not take glucosamine at the same time.

Pregnancy & Lactation:

Pregnancy
There are no adequate data from the use of glucosamine in pregnant women. From animal studies only insufficient data are available. Glucosamine sulphate should not be used during pregnancy.

Breastfeeding
There are no data available on the excretion of glucosamine into human milk. The use of glucosamine sulphate during breastfeeding is therefore not recommended as there is no data on the safety for the newborn.

Side Effect:
Cardiovascular: Peripheral oedema, tachycardia were reported in a few patients following larger clinical trials investigating oral administration in osteoarthritis. Causal relationship has not been established.

Central nervous system: Drowsiness, headache, insomnia have been observed rarely during therapy (less than 1%).

Gastrointestinal: Nausea, vomiting, diarrhea, dyspepsia or epigastric pain, constipation, heartburn and anorexia have been described rarely during oral therapy with glucosamine.

Skin: Skin reactions such as erythema and pruritus have been reported with therapeutic administration of glucosamine

Symptoms of Overdosage and Treatment:

Signs and symptoms of accidental or intentional overdose might include headache, dizziness, disorientation, arthralgia, nausea, vomiting, diarrhoea or constipation.

In case of overdose, treatment with glucosamine should be discontinued.

Route of Administration: Oral

Packing: 30 sachets x 1884mg per sachet

Storage Condition: Store below 30°C. Protect from light and moisture.

Shelf Life: Please refer to the packaging. Do not use beyond the expiry date. The information contained in this leaflet is limited. For further information, please consult your doctor or pharmacist.

Product Registration Holder:
Biofizz Marketing Sdn Bhd
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Manufacturer:
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Date of revision: September 2025