

Live-well®

OsteSAMIN™

1500

COMPOSITION:

Each 4g sachet contains:

Glucosamine Sulphate Potassium Chloride 1990mg equiv. to Glucosamine Sulphate 1500mg.

DESCRIPTION:

Powder: An Orange to Reddish powder with odour of orange flavour.

Solution: A clear orange solution with odour of orange flavour.

PHARMACODYNAMICS:

Glucosamine is a natural substance found in chitin, mucoproteins, and mucopolysaccharides. It is involved in the manufacture of glycosaminoglycan, which forms cartilage tissue in the body; glucosamine is also present in tendons and ligaments. Glucosamine must be synthesized by the body but the ability to do this decline with age. Glucosamine and its salts have therefore been advocated in the treatment of rheumatic disorders including osteoarthritis.

Glucosamine also acts to improve the viscosity of synovial fluid by increasing synovial fluid production, thereby providing lubricant activity.

PHARMACOKINETICS:***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 sulphate is eliminated as carbon dioxide via expired air.

INDICATION:

Adjunctive therapy for osteoarthritis.

ROUTE OF ADMINISTRATION:

Oral administration.

RECOMMENDED DOSE:

One sachet (dissolved in glass of water) to be taken once daily, preferably at meals.

CONTRAINDICATIONS:

Contraindicated in individuals who have hypersensitivity to glucosamine or to any of the excipients. As the active ingredient is obtained from seafood (shellfish), the product should not be given to patients who are allergic to shellfish.

WARNING AND PRECAUTION:

Glucosamine treats the underlying cause of osteoarthritis and the therapeutic effect can only be seen after 2-3 weeks. Therefore, it is advisable to take an analgesic/anti-inflammatory drug if required during the first 2-3 weeks of therapy with glucosamine.

Safety and effectiveness have not been established in children therefore children, should avoid using glucosamine.

Patients with severe hepatic or renal insufficiency should be monitored.

Derived from seafood, therefore should not be given to patients who are allergic to shellfish.

A doctor should be consulted in order to exclude the presence of other joint conditions/diseases for which an alternative treatment should be considered.

Effects on Ability to Drive and Use Machines

No effects on the ability to drive or to operate machines are expected.

INTERACTIONS WITH OTHER MEDICAMENTS:

Effects on glucose metabolism & antidiabetic agents:

It has been hypothesized that glucosamine may impair insulin secretion through competitive inhibition of glucokinase in pancreatic beta cells and/or alteration of peripheral glucose uptake. Glucosamine may increase insulin resistance and consequently affect glucose tolerance.

It may reduce antidiabetic agent effectiveness eg. when used with these antidiabetic agents: Acarbose, Acetohexamide, Chlorpropamide, Glipizidede, Glyburide, Metformin, Miglitol, Pioglitazone, Repaglinide, Rosiglitazone, Glimepiride , Tolbutamide, Troglitazone.

Glucosamine is likely safe in patients with well-controlled diabetes (HbA1c less than 6.5%) taking one or two oral antidiabetic medications or controlled by diet only. In patients with higher HbA1c levels or those taking insulin, monitor blood glucose levels closely/more frequently.

Reduced effectiveness when used with glucosamine: Doxorubicin, Etoposide , Teniposide

Warfarin

- Elevations of International Normalized Ratio serum values and potentiation of anticoagulant effects.

- If concomitant therapy is necessary, the patient's INR should be more closely monitored.

PREGNANCY AND LACTATION:

Available evidence is inconclusive or inadequate for use in pregnant or lactating mothers. Until more information is available, this product should only be used under medical supervision in pregnancy and lactating mothers if the potential benefit to the mother justifies the potential risk to the fetus. Administration during the first 3 months of pregnancy must be avoided.

SIDE EFFECTS:

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, diarrhoea, 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.

OVERDOSAGE:

No cases of accidental or intentional overdose are known. The animal acute and chronic toxicological studies indicate that toxic effects and symptoms of toxicity are not likely to occur, even after high overdoses.

STORAGE: Store in a dry place below 30°C. **SHELF-LIFE:** 3 years.

PRESENTATION: 1, 2, 3, 5, 7, 10, 12, 14, 15, 20 & 30 sachets

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