Three Legs Glucosamine Sulphate 500mg Capsule

Composition:
Each capsule 628mg contains:
Glucosamine Sulphate Sodium Chloride 628mg (equivalent to Glucosamine Sulphate 500mg)

Product Description: White colour powder is filled in scarlet bovine capsule. Capsule size: 0. No marking on the capsule.

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 declines with age. Glucusamine 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 sulfate is eliminated as carbon dioxide via expired air.

Indication: As adjuvant therapy for osteoarthritis.

Direction of use:
Best to be taken on an empty stomach (30 minutes before meals).

Light or moderate osteoarthritis symptoms:
1 capsule to be taken 2 times daily for at least 6 weeks or according to medical prescription.

Severe osteoarthritis symptoms:
Initial therapy: 1 capsule to be taken 3 times daily is recommended for at least 8 weeks.

Follow-up therapy:
Maintenance therapy should be followed for 3-4 months (or according to medical prescription) by administration of 1 capsule twice daily.

The treatment should be repeated every other 6 months or less according to medical prescription.

Contraindications:
Hypersensitivity to glucosamine sulphate. As the active ingredient is obtained from seafood (shellfish), the product should not be given patients who are allergic to shellfish.

Warnings and Precautions:
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.

Administration during the first three months of pregnancy must be avoided.

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

The administration in patients with severe hepatic or renal insufficiency should be made under medical supervision.

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.

Keep out of reach of children.

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.

Reduces effectiveness when use 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.

Statement on Usage During 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.

Adverse Effects/ Undesirable Effects:
Nausea, abdominal pain, indigestion, diarrhoea and constipation. In addition, headache, tiredness, rash, itching and flushing have been reported.

Symptoms and Treatment of Overdose:
Signs and symptoms of accidental or intentional overdose might include headache, dizziness, disorientation, arthralgia, nausea, vomiting, diarrhea or constipation.

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

Storage Conditions: Store below 30°C. Protect from moisture.

Shelf Life: 3 years

Dosage Form: Capsule

Packing Size: 60's, 120's, 180's, 500's, 1000's 10's x 6 blisters/ box, 10's x 10 blisters/ box, 10's x 12 blisters/ box, 10's x 18 blisters/ box, 10's x 30 blisters/ box, 10's x 50 blisters/ box, 10's x 100 blisters/ box

Manufactured by Product Registration Holder:
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