

shine® Osteojoint® Film Coated Tablet

Name and Strength of Active Substance(s):

Each film coated tablet contains:

Glucosamine HCl	500mg
Chondroitin Sulfate Sodium	440mg
(eq. to Chondroitin Sulfate 400mg)	
Methylsulfonylmethane (MSM)	400mg
This product contains Glucosamine derived from seafood and Chondroitin from bovine source.	

Product Description:

A white colour film coated elliptical tablet, one side impressed with a score.

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 synthesised by the body but the ability to do this declines 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.

Chondroitin is an acid mucopolysaccharide that is a constituent of most cartilaginous tissues. It is given orally in reactive arthritides such as gonococcal arthritis and given with glucosamine for its supposed chondroprotective action in bone, joint, and connective tissue disorders. Chondroitin is an important structural component of cartilage and provides much of its resistance to compression. This combination therapy works synergistically to stimulate cartilage cell growth and provide strength to cartilage.

Methylsulfonylmethane (MSM) is an organic sulphur-containing compound that occurs naturally in a variety of fruits, vegetables, grains and animals including humans. It blocks the inflammatory process and enhances the activity of cortisol, a natural anti-inflammatory hormone produced in the body. MSM is an effective natural analgesic and has been used as an application for pain relief over arthritis joints.

Pharmacokinetics:

Absorption: After oral administration, bioavailability of **glucosamine** is low due to first-pass hepatic metabolism of ~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 is 2.5 liters.

Metabolism: Liver, extensive. The first-pass effect in the liver in which more than 70% of glucosamine is metabolised.

Excretion: Renal excretion 10%; Faeces 11%.

Earlier studies using high molecular weight **chondroitin** concluded that there was no significant absorption of the high molecular weight version of chondroitin. More recent studies demonstrate that there is probably significant absorption of low molecular weight chondroitin. Absorption appears to occur from the stomach and small intestine. There is also an indication that some chondroitin, after absorption, does enter the joint space. In a study using depolymerized shark chondroitin, approximately 30% of the administered drug (as high and low molecular weight derivatives) was absorbed. Once absorbed, the chondroitin is incorporated into glycosaminoglycan-rich tissues such as joint cartilage.

Metabolism and excretion of **MSM** found the primary metabolite became detectable in serum approximately 2 hours after ingestion of MSM. With continued MSM ingestion, metabolite maintained a steady concentration in the serum. When MSM was stopped after 14 days, the mean metabolite concentration declined slowly over the subsequent 96 hours, and only trace amounts were detectable after 5 days. The decline in serum metabolite was linear, and its half-life appeared to be about 38 hours. Metabolite has been shown to persist in the blood up to 5 times longer than MSM.

Indication:

Used as adjuvant therapy for osteoarthritis.

Recommended Dosage:

Adults:

Light to moderate osteoarthritis symptoms:

Take 1 tablet, 2 times per day before meal, for a period of at least 6 weeks (or as directed by healthcare professional).

Severe osteoarthritis symptoms:

Initial therapy: Take 1 tablet, 3 times per day before meal, for a period of at least 12 weeks.

Maintenance therapy: Take 1 tablet, 2 times per day before meal, for a period of 3-4 months (or as directed by healthcare professional).

Route of Administration:

For oral administration only.

Contraindications:

Hypersensitivity to glucosamine, chondroitin or MSM.

As glucosamine is obtained from seafood, the product should not be given to patients who are allergic to seafood.

Warnings and Precautions:

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

chondroitin / MSM) are not meant to replace NSAIDs in cases of intense pain as this is a causal therapy.

Glucosamine may increase insulin resistance. Glucosamine increases insulin resistance in normal and experimentally diabetic animals. In these animals, intravenous glucosamine significantly decreases the rate of glucose uptake in skeletal muscle.

Those with type 2 diabetes and those who are overweight and have problems with glucose tolerance should have their blood sugar levels carefully monitored if they use glucosamine supplements.

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.

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

This product contains glucosamine derived from seafood, therefore should not be given to patients who are allergic to seafood.

This product contains chondroitin from bovine source.

Please consult your pharmacist / doctor before taking this product.

Interactions with Other Medicaments:

Effects on glucose metabolism and antidiabetic agents: It has been hypothesised 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 e.g. when used with these antidiabetic agents: acarbose, acetohexamide, chlorpropamide, glipizide, glyburide, metformin, miglitol, pioglitazone, repaglinide, rosiglitazone, glimepiride, tolbutamide and 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 sugar levels closely or more frequently.

Reduced effectiveness when used with glucosamine: doxorubicin, etoposide and teniposide.

Warfarin: Elevations of International Normalized Ratio (INR) serum values and potentiation of anticoagulant effects. If concomitant therapy is necessary, the patient's INR should be more closely monitored. There is a possibility that chondroitin may have anti-thrombotic activity. Those taking warfarin and those with haemophilia should exercise caution in its use.

Chondroitin should not be used concomitantly with chitosan.

Pregnancy and Lactation:

Available evidence is inconclusive or inadequate for use in pregnant or lactating mothers. Until more information is available, this product is not recommended for pregnancy and lactating mothers. 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.

Symptoms and Treatment of Overdose:

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 overdose.

Effects on Ability to Drive and Use Machine:

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

Storage Conditions:

Keep container tightly closed.

Store at temperature below 30°C.

Protect from light and moisture.

Keep out of reach of children.

Jauhkan daripada capaian kanak-kanak.

Shelf Life:

3 years.

Dosage Forms and Packaging Available:

Bottle of 60 tablets.

Registration No: MAL24096080X



Manufacturer and Product Registration Holder:

Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)

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