



**GLUCOSAMINE-500
TABLET**

COMPOSITION:

Each tablet contains:
Crystalline Glucosamine Sulphate
Potassium Chloride 665mg
equivalent to Glucosamine Sulphate 500mg

PRESENTATION:

Oblong, 18.8mm bone yellow tablet.

INDICATION:

As an adjunctive therapy in osteoarthritis.

PHARMACOLOGY:

Mechanism of Action:

Glucosamine sulphate stimulates the anabolic metabolism of osteocartilaginous tissues by stimulating the biosynthesis of the mucopolysaccharides that are the essential components of the cartilage ground substances. Glucosamine sulphate improves the viscosity of synovial fluid by increasing synovial fluid production, thereby providing lubricant activity. Therefore glucosamine sulphate has the therapeutic effects of reduce articular pain, improves the articular function and inhibits the articular degenerative process.

Pharmacokinetics:

Onset (oral) : 4 weeks

Absorption: Oral: 26%. After oral administration, bioavailability is low due to first-pass hepatic metabolism.

Distribution: Glucosamine is not protein-bound, but rather incorporates into plasma proteins (primarily globulins).

Metabolism: Glucosamine sulfate is rapidly desulfated following oral or parenteral administration; glucosamine is metabolized (predominantly in the liver) to smaller molecules and ultimately to carbon dioxide, water, and urea.

Excretion: 10% renal excretion. Approximately 11% of an orally administered dose of radiolabeled glucosamine sulfate is excreted in the faeces; most of this appears to be unabsorbed drug. Less than 1% of radioactivity after radiolabeled intravenous or intramuscular doses appears in the faeces.

Elimination half life: 70 hours.

DOSAGE AND ADMINISTRATION:

Best taken before meal.

Light or moderate osteoarthritis symptoms: 1 tablet twice daily for at least 6 weeks.

Severe osteoarthritis symptoms: Initially 1 tablet 3 times a day for at least 8 weeks.

Maintenance therapy should be followed for 3-4 months with 1 tablet twice daily. The treatment should be repeated every other 6 months or as directed by physician.

CONTRAINDICATIONS:

Contraindicated in patients sensitive to glucosamine sulphate and shellfish.

PRECAUTIONS:

As this is a causal therapy, Axcel Glucosamine-500 Tablet is not meant to replace NSAIDs in cases of intense pain. It is advisable to take an anti-inflammatory drug in the initial treatment of osteoarthritis together with glucosamine sulphate. Therapeutic effect can only be seen after approximately 1 week from the beginning. Patients with type 2 diabetes and those who are overweight and have problems with glucose tolerance should have their blood sugar carefully monitored. Children, pregnant women and nursing mothers should avoid using this preparation. Derived from seafood, therefore should not be given to patients who are allergic to shellfish.

Use in Pregnancy and Lactation:

Animal studies did not evidence any unfavourable effects on the reproductive functions or lactation. In the absence of such studies in humans, the product should only be used under medical supervision during pregnancy and lactation.

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.

DRUG INTERACTION:

Glucosamine may increase insulin resistance and consequently affect glucose tolerance. Diabetics who are under medical advisement, decide to use glucosamine will need to monitor their blood glucose and may need to adjust the doses of the medications they take to control blood glucose. This need to be done under medical supervision.

STORAGE:

Keep container well closed. Store below 30°C. Protect from light.

**KEEP OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK**

PACK QUANTITIES:

Available in blister pack of 10 x 10's.

Further information can be obtained from pharmacist, physician or the manufacturer.

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Product Registration Holder & Manufactured By:



Kotra Pharma (M) Sdn. Bhd.
No.1, 2 & 3, Jalan TTC 12, (60082-V)
Cheng Industrial Estate,
75250 Melaka, Malaysia.

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