DIMENSION LEAFLET

14.85 cm

21 cm

Text Area

Aetos

Osteotect
Powder for oral solution 1500mg

Composition:
Each sachet contains:

Glucosamine Sulfate Sodium Chloride 1884 mg
(eq. to Glucosamine Sulfate 1500 mg)

Product Description:
Appearance of Powder : White powder.

Appearance after reconstitution : Clear, colorless solution with a pineapple odor.

Pharmacodynamic:
Glucosamine possesses arthrotrophic metabolic activity by stimulating the anabolic metabolism of osteocartilageneous tissues via stimulation of the biosynthesis of the mucopolysaccharides (which are the essential components of the cartilage ground-substances) and of the bone mesenchymal tissues.

Glucosamine also acts to improve the viscosity of synovial fluid by increasing synovial fluid production, thereby providing lubricant activity. Glucosamine is therapeutically used in all forms of degenerative osteoarticular disease such as arthrosis and osteoarthritis (both subacute and chronic) with the following therapeutic effects: disappearance or reduction of articular pains, improvement of articular function, inhibition of regression of the degenerative process.

Pharmacokinetics:
Glucosamine is highly absorbable in the sulfate form and the sulfate component appears to potentiate the therapeutic effect of glucosamine therapy.

Pharmacokinetic studies show that glucosamine sulfate when taken orally, is well absorbed from the digestive tract at a rate approaching 90% and from there it is transported via the portal circulation to the liver. It appears that a significant fraction of the ingested glucosamine is catabolised by first-pass metabolism in the liver. Some uptake in the articular cartilage is seen in animal studies. Free glucosamine is not detectable in plasma.

Elimination of glucosamine is primarily through the urine, with a small amount of glucosamine or its derivatives eliminated in the faeces. The elimination half-life of glucosamine, which is incorporated into the plasma proteins, is about 68 hours after oral doses.

Indications:
As adjuvant therapy for osteoarthritis

Route of Administration:
Oral

Dosage:
For osteoarthritis: Dissolve 1 sachet with a glass of water and take it once daily. Glucosamine is not used for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after some weeks of treatment or sometimes even longer. If your symptoms do not get better after 2- 3 months, you should speak to your doctor or pharmacist as you may need to consider other treatment.

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

Warnings and Precautions:
- Long term oral administration of this drug may cause high blood sugar level, therefore should periodically monitor blood glucose when administering this drug.
- Diabetes patients, use as prescribed by the physician.
- Glucosamine may enhance anti-coagulant activity of warfarin. Patients with combination therapy with glucosamine and warfarin should monitor INR level and be aware of bleeding.

***Keep out of reach of children. Jauhkan daripada capaian kanak-kanak.**

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- Derived from Seafood. Patients with an allergy to shellfish and shellfish products should avoid administering glucosamine.
- Patients with asthma may be at risk for an asthma exacerbation when taking glucosamine-chondrotin sulfate.
- Unsuitable for Phenylketonurics.
- Glucosamine Sulfate is a causal therapy and the therapeutic effect can only be seen after approximately 1 week from the beginning. Therefore, in case of intense pains, it is advisable to take an anti-inflammatory drug in addition during the first days of treatment with Glucosamine.
- Concomitant use in patients with severe hepatic and renal insufficiency should be made under medical supervision.

Use in pregnancy and lactation:
Glucosamine should not be taken during pregnancy and lactation because scientific evidence for safe use is not available.

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:
- Hypoglycaemic agents : Close monitoring of blood sugar levels 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 agents.
- 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.

Symptoms & Treatment of Overdose :
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.

Storage condition :
Store below 30°C

Pack Size :
Sachets made of aluminium, packed in cartons containing 10, 25, 30, 50 or 100 sachets.

Product Registration Holder:

Aetos Pharma Sdn Bhd
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56000 Kuala Lumpur,
Wilayah Persekutuan Kuala Lumpur,
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Manufactured by :

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