NUVANTA

Chondrosamine

Glucosamine HCl 500mg • Chondroitin Sulphate 400mg

Description:
This tablet is white to off white, oval shaped, plain, 16.6mm length film coated tablets.

Composition:
Each film-coated tablet contains Glucosamine hydrochloride 500mg and Chondroitin sulphate sodium 445mg (Equivalent to chondroitin sulphate 400mg).

Pharmacodynamics:
Glucosamine Hydrochloride - Its metabolic actions on articular cartilage include the stimulation of proteoglycan (PG) synthesis by cultivated human chondrocytes & protection against the metabolic impairment induced by some NSAIDs in vitro. Glucosamine HCl appears to affect specifically the synthesis of monomeric PG aggregates, since lower size PG identified by gel filtration on Sepharose C1 -2B only represent a minor portion of the total immunoreactive PG. These findings demonstrated that in normal human adult chondrocytes in vitro, Glucosamine HCl increases aggregan protein mRNA. (Jimenez et al., Osteoarthritis & Cartilage 1997, Vol 5, Suppl A:72)

Hellio et al. observed that Glucosamine induced an increase of protein synthesis in human osteoarthritis chondrocytes in vitro. Based on these results, it is suggested that Glucosamine acts through an increase of sulphated glycosaminoglycans synthesis, which, in turn, induces PG core protein production by human chondrocytes. Such an explanation is supported by the fact that Glucosamine stimulates SO4 uptake in rat articular cartilage in vitro. Similar results were also achieved in ex vivo experiments following treatment of animals for 14 days with oral Glucosamine. Analyzed together, these experiments suggest that Glucosamine is able to stimulate glycosaminoglycans & the synthesis of PG. Glucosamine has also showed in vitro anti -catabolic properties suppressing collagenase activity & increasing the diminished adhesion of chondrocytes to fibronectin in fibrillated cartilage (Annefield M., Preclinical testing of the structure-modifying potential of Glucosamine in osteoarthritis. Presented at Eular 97). Glucosamine has been shown to possess anti -inflammatory activities in different in vivo animal models without inhibiting the synthesis of prostaglandins (Muller -Fabender H, Osteoarthritis & Cartilage (1994) 2, 61-69.

Chondroitin Sulphate Sodium (CS) - The therapeutic activity of CS in osteoarthritic patients can be due fundamentally to at least four possible action mechanisms: 1) anti-inflammatory activity at a level of the cellular components of inflammation; 2) metabolic effects on the synthesis of proteoglycans and hyaluronic acid favoring its synthesis; 3) decrease of the catabolic activity of chondrocytes inhibiting some proteolytic activities (collagenase, elastase, proteoglycans, etc.) among others; 4) inhibition of nitric oxide. It has been postulated that probably nitric oxide exerts a damaging effect on the articular cartilage, for osteoarthritic cartilage releases higher quantities of nitric oxide than normal cartilage.

A study by Blanco et al. studied the effect of different extracellular matrix components: chondroitin sulphate, collagen type II, glucosamine sulphate, glucosamine hydrochloride, on nitric oxide production by human osteoarthritis chondrocytes. From all the extracellular matrix components tested, only CS was able to reduce the nitric oxide synthesis (Osteoarthritis & Cartilage (1997) 7, (Supplement A):S16:62). This mechanism of action explains the therapeutic activity of CS shown in osteoarthritis patients.

Pharmacokinetics:
Upon consumption of this product, the tablet disintegrates in the stomach to release glucosamine. About 90% of glucosamine administered orally as a glucosamine salt gets absorbed from the small intestine and from there it is transported via portal circulation to the liver. Some amount of the ingested glucosamine is catabolized in liver while some is taken up in the joints. Exact percentage that are catabolized or delivered to the joints are not known. Absorption of chondroitin sulphate occurs both from the stomach and small intestines. There are indications from studies which says after absorption sulphate does enter the joint space.

Indications:
As adjuvant therapy for osteoarthritis.

Route of administration: Oral

Dosage and Administration:
Light to Moderate Osteoarthritis Symptoms: Take 1 tablet twice daily, 15 minutes before meals for at least 6 weeks (or according to medical prescription).

Severe Osteoarthritis Symptoms:
Initial Therapy: Take 1 tablet 3 times daily, 15 minutes before meals during a period of at least 8 weeks.

Follow-up Therapy: Take 1 tablet twice daily, 15 minutes before meals. Maintenance therapy should be followed for 3-4 months by administration of 1 tablet twice daily.

Long-term Treatment: The treatment should be repeated every other 6 months or less according to medical prescription.

Glucosamine is a causal therapy and the therapeutic effect can 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.

Contraindications:
Contraindicated to those who are hypersensitive to glucosamine or other ingredient in the product.

Warning & Precautions:
Source of chondroitin: Bovine
Source of glucosamine: Crustacean shells

This product contains glucosamine. Those with type 2 diabetics and those who have problems with glucose tolerance whom consumed glucosamine and anti-inflammatory drug (in case of severe pain), please ensure that their blood sugar carefully monitored during the first day of the treatment. Glucosamine is not meant to replace NSAIDS in cases of intense pain as this is a causal therapy.

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

Interactions with Other Medicaments:
Diabetic's patients should take glucosamine under medical supervision.
There is a possibility that chondroitin sulphate may have antithrombotic activity.
Those taking warfarin and those with hemophilia should exercise caution in its use. Chondroitin should not be used concomitantly with chitosan.

Pregnancy & Lactation:
Pregnancy and lactation, as for other drugs, this tablet should be given under medical supervision. This product contains chondroitin sulphate which is not recommended for children, pregnant woman and nursing mothers.

Side Effects / Adverse Reactions:
Mild gastrointestinal complaints such as heartburn, epigastric distress, nausea and diarrhea have been reported. No sulfa-allergic reactions, or other allergic reactions have yet been reported.

1. 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.

2. Central nervous system:
Drowsiness, headache, insomnia have been observed rarely during therapy (less than 1%).

3. Gastrointestinal:
Nausea, vomiting, diarrhea, dyspepsia or epigastric pain, constipation, heartburn and anorexia have been described rarely during oral therapy with glucosamine.

4. 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 overdoses.
However, In the event of acute overdose, the patient should be observed closely and symptomatic treatment should be initiated.

Storage Conditions:
Store below 30°C in a dry place away from direct sunlight.

Shelf-life: 3 years

Pack Sizes: In containers of 10's, 20's, 30's, 40's, 50's, 60's, 90's, 100's, 120's, 150's or 180's. Not all pack sizes are marketed.

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Marketed by:
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The information in this leaflet is limited. If in doubt, please consult your physician or pharmacist.