# Cartilex® Plus

Glucosamine Sulfate and Chondroitin Sulfate

# Composition

Cartilex® Plus tablet: Each coated tablet contains Glucosamine Sulfate Potassium Chloride USP 995.04 mg equivalent to Glucosamine Sulfate 750 mg and Chondroitin Sulfate Sodium USP 660 mg equivalent to Chondroitin Sulfate 600 mg.

## **Pharmacology**

**Cartilex® Plus** is the preparation of Glucosamine Sulfate and Chondroitin Sulfate which are naturally occurring non-toxic biochemical substances that play a key role in cartilage formation and repair.

#### Mechanism of action

Glucosamine: Glucosamine is a normal constituent of polysaccharide chains of cartilage matrix and synovial fluid glucosaminoglycans. It stimulates the synthesis of physiological glycosaminoglycans and proteoglycans by chondrocytes and hyaluronic acid by synoviccytes. Glucosamine Sulfate also inhibits the activity of cartilage destroying enzymes such as collagenase and phospholipase A2, as well as the generation of other tissue damaging substances such as superoxide radicals or the activity of lysosomal enzymes that contributes to its mild anti-inflammatory effects.

Chondroitin Sulfate: Chondroitin Sulfate increases the synthesis of cartilage matrix components such as hyaluronic acid and proteoglycans and reduces the degradation of cartilage matrix components, specially collagen II, glycosaminoglycans and proteoglycans reduces necrosis and apoptosis of chondrocytes. Chondroitin Sulfate also reduces the activity of collagenase, N-acetylglucosaminidase, aggrecanase 1 and 2, matrix metalloproteinase (MMP) 3, MMP-9, MMP-13, MMP-14, cathepsin B and elastase and elicits an anti-inflammatory effect through diverse mechanisms.

## **Pharmacokinetics**

Glucosamine: After oral administration, approximately 90% of Glucosamine is absorbed from gastrointestinal tract. The absolute bioavailability after a single oral dose of Glucosamine is 25%, due to first pass effect in the liver in which more than 70% of Glucosamine is metabolized. Only 11% of the administered radioactivity is excreted in feces.

Chondroitin Sulfate: It is not rapidly absorbed in the gastrointestinal tract and a high content of Chondroitin Sulfate is found in the synovial fluid and cartilage. The bioavailability of Chondroitin Sulfate ranges from 15% to 24% of the orally administered dose.

## Indication

Cartilex® Plus is indicated for the treatment of osteoarthritis of knee, hip, spine, hand and other locations as a dietary supplement. It is also beneficial in rheumatoid arthritis, sport injuries, migraine, different skin problems (e.g., psoriasis), vascular complications (e.g., atherosclerosis), kidney stones and inflammatory bowel disease (e.g., ulcerative colitis, leaky gut syndrome).

### Dose and administration

Route of administration: Cartilex® Plus should be taken in oral route. The recommended dose of Cartilex® Plus is 1 tablet two times daily or as directed by the physician.

## Contraindication

This combination is contraindicated in patients with known hypersensitivity to glucosamine sulfate and chondroitin sulfate or any components of this product. It is also contraindicated in patients with prostate cancer or are those that are at high risk of developing it.

# Warning and precaution

Diabetic patients are advised to monitor blood glucose levels regularly while taking glucosamine. No special studies were formed in patients with renal and hepatic insufficiency. The toxicological and pharmacokinetic profile of this combination does not indicate limitations for these patients. However, administration to these patients with severe hepatic or renal insufficiency should be under appropriate medical supervision.

## Side effect

The most common side effects of this combination are stomach upset, nausea or diarrhea and it is usually disappear when the tablet is taken with meals.

# Use in pregnancy and lactation

Women who are pregnant or who could become pregnant should not supplement with this combination. They have not been studied enough to determine their effects on a developing fetus, and no studies have evaluated the use of this combination during pregnancy or lactation. It should be taken with caution and medical advice during pregnancy and lactation.

#### Use in children and adolescents

The safety and effectiveness of children and adolescents under the age of 18 years have not been established.

#### Drug interaction

**Drug interaction with medication:** Increase INR has been reported during treatment with glucosamine and coumarin anticoagulants. Patients treated with coumarin anticoagulants should therefore be monitored closely when initiating or ending glucosamine therapy. Concurrent treatment with glucosamine may increase the absorption and serum concentration of tetracyclines. It is safe to take glucosamine with blood pressure medications, non-steroidal anti-inflammatory and for diabetics on hypoglycemic agents (but close monitoring of blood sugar levels is recommended).

**Drug interaction with food:** Not applicable **Drug interaction with others:** Not applicable

#### Overdose

There is no data available regarding overdose of this combination.

# Storage

Store in a cool (below 30°C) and dry place protected from light. Keep away from the reach of children.

# Packing

Cartilex® Plus tablet: Carton of 30 tablets in Alu-Alu blister.

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