

COMPOSITION: Contilex® tablet: Each film coated tablet contains Glucosamine Sulfate 250 mg as Glucosamine Sulfate Potassium Chloride USP & Chondroitin Sulfate 200 mg as Chondroitin Sulfate Sodium USP.

PHARMACOLOGY: Glucosamine (2-amino-2-deoxy-alpha-D-glucose) is a natural amino-sugar, produced by the body and found in certain foods. It is the most fundamental building block required for biosynthesis of glycosaminoglycans (GAGs) like Hyaluronic Acid, Keratan Sulfate, and Chondroitin Sulfate. GAGs binds with protein and form proteoglycans, the essential building block of articular cartilage. When cartilage in a joint deteriorates, Osteoarthritis develops. It also helps to form ligaments, tendon, nails, and various other connective tissues. When we take artificially synthesized Glucosamine Sulfate supplement, it increases Glucosamine level in the body, thus facilitates production and repair of cartilage. Glucosamine also activates chondrocytes in the cartilage which help produce GAGs and proteoglycans.

Chondroitin Sulfate is a glycosaminoglycan (acid muco-polysaccharide) found in connective tissue, especially in the articular cartilage of all mammals. Chondroitin Sulfate supplement acts similarly as Glucosamine Sulfate, since it also provide substrate for proteoglycans. Chondroitin also protects existing healthy cartilage from premature decline by preventing the MMP (Matrix metalloproteinase) enzyme that breakdowns the proteoglycans.

Combining Glucosamine with Chondroitin Sulfate shows synergistic effect. Data supports that this combination has been shown to be very much effective in severe cases of Osteoarthritis that treats both sign and symptoms of Osteoarthritis & modifies disease progression. It prevents Osteoarthritis in case of normal adults. In Osteoarthritic pain it is as effective as NSAIDs with significantly better tolerability and clinical compliance. It is also helpful during the repair phase of musculo-skeletal soft tissue injuries such as tendon or ligament strains.

INDICATION: Treatment of Osteoarthritis of fingers, shoulder joints & weight bearing joints of the body. As a dietary supplement to prevent Osteoarthritis.

## DOSAGE AND ADMINISTRATION

1 - 2 tablets, three times daily. Dose may be adjusted according to the response of the drug and body weight. Doses can be tapered after 60 days as per requirement of the individual and for cost convenience. Typical dosage recommendation, based on body weight is as follows-

Under 54 Kg: 800 mg Chondroitin Sulfate & 1000 mg Glucosamine Sulfate per day

 $54~\mbox{Kg}$  -  $91~\mbox{Kg}$ :  $1200~\mbox{mg}$  Chondroitin Sulfate & 1500~\mbox{mg} Glucosamine Sulfate per day

Over 91 Kg: 1600 mg Chondroitin Sulfate & 2000 mg Glucosamine Sulfate per day

CONTRAINDICATION: There is no known contraindication to Glucosamine or Chondroitin. But proven hypersensitivity to these ingredients is a contraindication.

PRECAUTION: Patients with Diabetes Mellitus are advised to monitor blood glucose levels regularly when taking Glucosamine. No special studies were formed in patients with renal or hepatic insufficiency. The toxicological and pharmacokinetic profile of Glucosamine and Chondroitin does not indicate limitations for these patients. However, administration to patients with severe hepatic or renal insufficiency should be under appropriate medical supervision. Children should not be supplemented with Glucosamine and Chondroitin.

SIDE EFFECT: Safety studies with Glucosamine Sulfate & Chondroitin Sulfate show no demonstrable side effects. Rarely occurring side effects (such as, mild & reversible intestinal flatulence) are almost like placebo.

USE IN PREGNANCY & LACTATION: Women who are pregnant or who could become pregnant should not supplement with Glucosamine Sulfate or Chondroitin Sulfate. Glucosamine and Chondroitin has not been studied enough to determine their effects on a developing fetus. No studies have evaluated the use of Glucosamine and Chondroitin during pregnancy or lactation. It should be taken with caution and medical advice during pregnancy and lactation.

DRUG INTERACTION: There have been no reports of significant drug interactions of Glucosamine and Chondroitin with Antibiotics/ Antidepressants/ Antihypertensives/ Nitrates/ Antiarrythmics/ Anxiolytic/ Hypoglycemic agents/ Antisecretives/ Antiasthmatics. Chondroitin may enhance the blood thinning effects of anticoagulants like Warferine, Heparine.

PHARMACEUTICAL PRECAUTION: Protect from light and moisture. Keep in dry and cool place.

HOW SUPPLIED: Contilex" Tablet: Box containing 5x6 tablets in Alu-Alu blister pack.