

# Cartigen<sup>TM</sup> PLUS

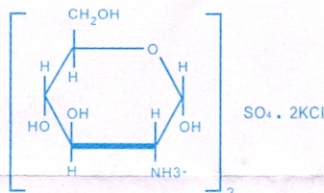
(Glucosamine + Chondroitin)

Film-Coated Tablets

750mg+600mg

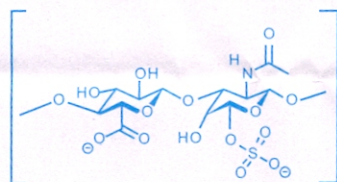
## DESCRIPTION

Glucosamine sulfate and chondroitin sulfate are the active ingredients of CARTIGEN PLUS (Glucosamine sulfate + Chondroitin sulfate) tablets. Glucosamine and chondroitin are naturally occurring structural components. Glucosamine is an amino sugar synthesized in the body from L-glutamine and glucose. Glucosamine stimulates the manufacture of glycosaminoglycans, important components of the cartilage needed for healthy joints. Commercial sources of glucosamine are from the exoskeleton of certain shellfish and are available as glucosamine sulfate, glucosamine hydrochloride, and N-acetyl-Glucosamine. The sulfated form may most effectively incorporate sulfur into the cartilage. Chemically glucosamine is Bis (D-Glucose, 2-amino-2-deoxy-), sulfate potassium chloride complex. The molecular formula is  $(C_6H_{14}NO_5)_2 \cdot SO_4 \cdot 2KCl$  and the structural formula is:



Glucosamine Sulfate

Chondroitin sulfate is a sulfated glycosaminoglycans (GAG) composed of a chain of alternating sugars (N-acetylgalactosamine and glucuronic acid). It is usually found attached to proteins as part of a proteoglycan. Chondroitin sulfate is an important structural component of cartilage and provides much of its resistance to compression. Along with glucosamine, chondroitin sulfate has become a widely used dietary supplement for treatment of osteoarthritis. Its structural formula is as follows:



Chondroitin Sulfate

## QUALITATIVE & QUANTITATIVE COMPOSITION

CARTIGEN PLUS (Glucosamine sulfate + Chondroitin sulfate) tablets are available for oral administration as:

CARTIGEN PLUS (Glucosamine sulfate + Chondroitin sulfate) tablets 750mg+600mg

Each film-coated tablet contains:

Glucosamine sulfate USP..... 750mg

Chondroitin sulfate USP..... 600mg

## CLINICAL PHARMACOLOGY

### Mechanism of Action

#### Glucosamine sulfate

The primary biological role of glucosamine sulfate in reversing joint degeneration appears to be directly due to its ability to act as an essential substrate for and to stimulate the biosynthesis of glycosaminoglycans and the hyaluronic acid backbone needed for the formation of proteoglycan found in the structural matrix of the joint. Osteoarthritis results from an imbalance between the rate of synthesis and the rate of degradation of cartilage proteoglycans and where degradation exceeds synthesis. If this is the case, then increasing the availability of glucosamine will in turn increase the production of cartilage proteoglycan and thus, potentially decrease joint pain and increase flexibility.

#### Chondroitin sulfate

Chondroitin sulfate stimulates the synthesis of hyaluronic acid which is the lubricant for joints as well as a major component of connective tissue in the skin.

### Pharmacokinetics

#### Glucosamine sulfate

After oral administration about 90% of glucosamine is absorbed from GI tract. The plasma levels as shown by radioactivity are smaller than that by parenteral administration suggesting a hepatic first-pass effect. It is also demonstrated that glucosamine diffuses well into several tissues including structures like bones and articular cartilage.

#### Chondroitin sulfate

Chondroitin sulfate is larger and more poorly absorbed; <10% intestinal absorption compared to 90% for glucosamine sulfate.

## THERAPEUTIC INDICATIONS

CARTIGEN PLUS (Glucosamine sulfate + Chondroitin sulfate) is indicated for the relief of osteoarthritis, a progressive disease of cartilage degeneration. It is used as a dietary supplement to decrease pain and improve mobility in people suffering from osteoarthritis. It is also a support for healthy joints and connective tissues. It may be used to prevent or postpone the development of osteoarthritis in certain groups, such as the elderly and the athletes. Other recommended uses of CARTIGEN PLUS (Glucosamine sulfate + Chondroitin sulfate) are tendonitis and bursitis.

## DOSAGE AND ADMINISTRATION

Daily doses of CARTIGEN PLUS (Glucosamine sulfate + Chondroitin sulfate) tablets are:

Weight	Glucosamine	Chondroitin
(Pounds)	(mg)	(mg)
< 120	1000	800
120 - 200	1500	1200
> 200	2000	1600

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**Adults:** Two tablets per day preferably with meals or as directed by the physician.  
If there is no effect within 12 weeks of treatment then discontinue the treatment.

### ADVERSE EFFECTS

No major adverse reactions have been reported with glucosamine sulfate and chondroitin sulfate. Possible side effects of glucosamine include nausea, diarrhoea, heartburn, drowsiness, skin rash and headache.

### CONTRAINDICATIONS

Hypersensitivity to shellfish or any of the ingredients.

### PRECAUTIONS

**Pregnancy, nursing women, children and elderly patients:**  
Pregnant women and those who wish to become pregnant; children, very elderly people and nursing women should avoid glucosamine since no studies among these specific populations exist.

**Patients taking blood-thinners:**

Patients taking blood-thinners should be extremely careful if they take glucosamine combined with chondroitin sulfate. Chondroitin is chemically similar to blood-thinning drugs such as heparin, warfarin, and even aspirin, and could cause excessive bleeding.

**Diabetics, renal impairment, peptic ulcer:**

Caution should be used with those who have diabetes, renal impairment and active peptic ulcer disease.

### Drug Interactions

No major drug interactions have been reported.

### STORAGE

Store below 30°C.  
Protect from sunlight & moisture.  
The expiration date refers to the product correctly stored at the required conditions.

### HOW SUPPLIED

CARTIGEN PLUS (Glucosamine sulfate + Chondroitin sulfate) tablets 750mg+600mg are available in blister packs of 14 tablets.

**Keep out of reach of children.**

Please read the contents carefully before use.  
This package insert is continually updated from time to time.

Manufactured by:



**Getz**  
pharma  
(PVT) LIMITED  
www.getzpharma.com

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K.I.A., Karachi,  
Pakistan

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