

## Summary of Product Characteristics

### 1. NAME OF THE MEDICINAL PRODUCT

**Glucosamine Plus** film-coated tablets.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each **Glucosamine Plus** film coated tablet contains:

Glucosamine Hydrochloride 500 mg

Chondroitin Sulfate Sodium 400 mg

For the full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM:

Film-coated tablets

White oval biconvex film coated tablet, length 19.3 mm ( $\pm 5.0\%$ ), width 9 mm ( $\pm 5.0\%$ )

### 4. CLINICAL PARTICULARS:

#### 4.1- Therapeutic indications:

**Glucosamine Plus** is indicated in joint deterioration.

Patients who are experiencing changes in joint flexibility or function should consult a healthcare professional, as **Glucosamine Plus** is more effective when used in the early stages of joint deterioration. Early action is always the best advice.

#### 4.2- Posology and method of administration:

Healthcare professionals may provide guidance on weight management, physical activity, and the use of Glucosamine Plus as part of the treatment plan.

Suggested daily intake: One film coated tablet three times daily with a full glass of water.

Usually, positive changes occur in one or two months.

After one month of treatment, the dosage may be reduced gradually, as advised by the healthcare professional.

Patients with pre-existing medical conditions or known allergies requiring medical attention should consult a Healthcare professional before initiating treatment with any medicinal product.

#### 4.3- Contraindications:

- Children, women who are pregnant and women who could become pregnant or nursing mothers should not take this medicinal product.
- People who are sensitive to any of the components should not take this drug.

#### 4.4- Special warnings and precautions for use:

- The recommended dose should not be exceeded.

Although not enough studies have been done on glucosamine hydrochloride and chondroitin sulfate to know all of the necessary precautions, the following groups of people should be especially careful when considering this medicinal product:

- Because glucosamine is an amino sugar, people who have diabetes should check their blood sugar levels more frequently if they take this medicinal product.
- Patients with hypercholesterolemia and gastric ulcer should take this drug with care.
- Patients who are taking chondroitin sulfate in addition to a blood-thinning medication or daily aspirin therapy, have their blood clotting time checked more often. This medicinal product is similar in structure to the blood-thinning drug heparin, and the combination may cause bleeding in some people.
- The medicinal product should be administered with caution to patients with bleeding, with a predisposition to bleeding, and with bronchial asthma.

#### 4.5-Interactions with other medicinal products and other forms of interaction:

Patients should inform their healthcare professional if they are currently taking or have recently taken any other medicinal products.

**Glucosamine Plus** enhances the action of antiaggregants, fibrinolytic agents as well as coumarin anticoagulants (e.g. warfarin) which may lead to bleeding.

#### 4.6-Fertility, pregnancy and lactation:

Women who are pregnant and women who could become pregnant or nursing mothers should not take this medicinal product.

#### 4.7-Effects on ability to drive and use machines:

No studies have been performed. This medicinal product is not expected to have an effect on the ability to drive or use machines.

#### 4.8-Undesirable effects:

The most common side effects of glucosamine hydrochloride and chondroitin sulfate are increased intestinal gas and softened stools.

If any unusual or new symptoms occur during treatment, patients should seek medical advice.

#### 4.9-Overdose:

No data or reports available on the overdose of glucosamine Hydrochloride or Chondroitin Sulfate in humans.

### 5. Pharmacological properties:

#### 5.1-Pharmacodynamic properties:

Pharmacotherapeutic group: Other anti-inflammatory and antirheumatic agents, non-steroids

ATC code: M01AX

**Glucosamine Plus** contains Glucosamine Hydrochloride and Chondroitin Sulfate Sodium. These substances are found naturally in the body. Glucosamine is a form of amino sugar that is believed to play a role in cartilage formation and repair. Chondroitin sulfate is a part of a large protein molecule (proteoglycan) that gives cartilage elasticity.

**Glucosamine Plus** can slow down cartilage deterioration and protect cartilage cells from breakdown. **Glucosamine Plus** helps reduce joint pain and stiffness by using ingredients that are safe, effective and easily absorbed.

#### Mechanism of action

The two main ingredients in **Glucosamine Plus**, chondroitin sulfate and glucosamine hydrochloride, stimulate the production of cartilage. In younger, healthier individual cartilage cells would normally accomplish this task. However, as one ages, cartilage cells die off and are not replaced. This starts a cycle of destruction in the cartilage. There are also enzymes present that degrade cartilage.

Glucosamine hydrochloride stimulates cartilage production while chondroitin sulfate inhibits enzymes that break down cartilage. Chondroitin sulfate slows the progression of cartilage deterioration as well as reduces joint pain.

#### 5.2 Pharmacokinetic properties:

**Chondroitin sulfate:** After oral administration, more than 70% of the dose is absorbed in the gastrointestinal tract (GIT). Bioavailability is about 13%. The maximum concentration (C<sub>max</sub>) in the blood plasma is achieved 3-4 hours after a single oral dose. Accumulates in the synovial fluid (C<sub>max</sub> after 4-5 hours). Excreted by the kidneys.

**Glucosamine:** Bioavailability after oral administration is 25% (the effect of the "first pass" through the liver). The highest concentrations are found in the liver, kidneys and articular cartilage. About 30% of the dose taken persists for a long time in bone and muscle tissue. It is excreted mainly in

urine unchanged.

### **5.3-Preclinical safety data:**

Not applicable.

## **6. Pharmaceutical particulars:**

### **6.1-List of excipients:**

#### Tablet core:

Microcrystalline cellulose

Povidone

Croscarmellose sodium

Colloidal silicon dioxide

Magnesium stearate

#### Tablet coating:

Hydroxypropyl methylcellulose

Polyethylene Glycol

Talc

Titanium Dioxide

### **6.2 Incompatibilities:**

Not applicable.

### **6.3 Shelf life:**

3 Years

### **6.4 Special precautions for storage:**

Store below 25°C.

Keep out of the reach of children.

The medicinal product shouldn't be used after the expiry date which is stated on the label or carton.

The expiry date refers to the last day of that month.

### **6.5 Nature and contents of container**

Each pack contains a leaflet with white plastic bottle containing 30, 60 or 100 film coated tablets with a desiccant bag. Each plastic bottle is supplied with a child-resistant screw cap and an aluminum seal.

### **6.6 Special precautions for disposal and other handling**

This medicinal product should not be disposed of via wastewater or household waste. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7.MANUFACTURER:**

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## **8. MARKETING AUTHORIZATION HOLDER:**

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## **9.DATE OF FINAL REVISION OF THE TEXT:**

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