Summary of Product Characteristics (SPC)

Glucosamine Compound
Film Coated Tablets

1- Name of the medicinal product: Glucosamine Compound

2-Qualitative and quantitative composition:  
Each film coated tablet contains:  
Glucosamine Sulfate 500 mg  
Chondroitin Sulfate 400 mg  
Ascorbic acid 100 mg

3- Pharmaceutical Form: Film coated tablets.

4- Clinical particulars:  

4.1 Therapeutic indications:  
All types of Osteoarthritis.  
Osteoarthritis during recovery of injuries & after operations.  
Dystrophy of joints associated with aging.  
As preventive measure in cases of overburdening of joints, in intensive sport and stress injury.  
Poor work posture, heavy lifting, generally during aging.

4.2 Posology and method of administration:  
One tablet three times daily.

4.3 Contraindications:  
- Known hypersensitivity to any of the product's components  
- Do not take glucosamine compound if you are taking coumarin anticoagulant especially warfarin.  
- Glucosamine must not be given to patient who are allergic to shellfish as the active substance is obtained from shellfish.

4.4 Special warnings and precautions for use:
In patients with impaired glucose tolerance, monitoring of the blood glucose levels and, where relevant, insulin requirements is recommended before start of treatment and periodically during treatment.

Exacerbation of asthma symptoms after initiation of glucosamine have been described (symptoms resolved after withdrawal of glucosamine), therefore, asthmatic patients starting on glucosamine should be aware of potential worsening of symptoms.

In patients with known risk factor for cardiovascular disease, monitoring of the blood lipid levels is recommended, since hypercholesterolemia has been reported in a few cases in patients treated with glucosamine.

4.5 Interaction with other medicinal products and other forms of interaction:

- Increased effect of coumarin anticoagulants (e.g warfarin) during concomitant treatment with glucosamine has been reported. 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, but the clinical relevance of this interaction is probably limited.
- Due to limited documentation on potential drug interactions with glucosamine, one should generally be aware of altered response or concentration of currently used medicinal products.

4.6 Fertility, pregnancy and lactation:
No clinical data on exposed pregnancy & lactation are available. Consult a health care practitioner prior to use if you are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines:
Glucosamine compound has no influence on ability to drive and use machines

4.8 Undesirable effects:
Rarely, gastrointestinal disturbances, mild headache and skin rash.

4.9 Overdose:
No cases of accidental or intentional overdose are known. The animal acute and chronic toxicological studies indicate that toxic effects and symptoms are unlikely to occur at doses up to 200 times the therapeutic dose. However if overdose occurs treatment should be symptomatic and standard supportive measures should be adopted as required.

5-Pharmacological properties:

5.1 Pharmacodynamic properties:
Glucosamine compound tablet is formulated to meet the natural challenge of arthritis, its main components glucosamine sulphate and chondroitin sulphate are combined in a therapeutic dosage for optimal conditions to reconstruct the cartilage matrix, while ascorbic acid works by mopping free oxygen radicals thus aiding in the prevention of cartilage damage.

Glucosamine sulphate, an endogenous amitiosaccharide made up of glucose and an amino acid, glutamine, is an important part of the mucopolysaccharides which provide structure to the bone, cartilage, skin and other tissues. It helps the manufacture of collagen which is the protein part of the fibrous substance that holds joints together, by improving joint function; it helps reduce the pain associated with osteoarthritis.

Chondroitin sulphate is the most abundant glycosaminoglycan localized in cartilage, it is derived from the sulphated polymer D-glucuronic acid beta (1-3) D-N- acetyl galactosamine beta (1-4), chondroitin facilitates lubrication in the joints resulting in freedom of movement, it sweeps nutrients into the cartilage and the fluid acts like a spongy shock absorber.

Glucosamine and chondroitin work synergistically to help stimulate cartilage production and control cartilage damaging enzymes and therefore help maintain equilibrium between cartilage catabolic and anabolic processes, Glucosamine compound tablet is thus effective in treating the disease at the cellular level.

Ascorbic acid works by mopping up free oxygen radicals thus aiding in the prevention of cartilage damage.

5.2 Pharmacokinetic properties:

Glucosamine: Animal and human studies, carried out with 14C-labelled glucosamine, have shown that after oral administration, glucosamine is rapidly and almost completely absorbed at systemic level (about 90% of the radioactive dose is absorbed). The terminal elimination half-life of glucosamine from plasma has been estimated as around 15 hrs. Experimental results show that the kidneys significantly contribute to the elimination of glucosamine and/or of its metabolites.

Chondroitin Sulfate: The bioavailability after oral administration is 15-24%. A 10% of absorbed chondroitin sulfate appears in unmetabolized form and 90% as depolymerized derivatives with lower molecular weight, as a result of first-pass effect metabolism. Distribution volume of chondroitin sulfate is relatively low. In humans, chondroitin sulfate has shown to have affinity for joint tissues. At least 90% of chondroitin sulfate dose is 1st metabolized by lysosomal sulfateses, and after that it is depolymerized by hyaluronidases ie, β-glucuronidases and β-N-acetyl hexose amidases. Liver, kidneys and other organs are involved in the depolymerization of chondroitin sulfate.

On average, chondroitin sulfate remains in the body 5-15 hrs. Main part of chondroitin sulfate and its depolymerized derivatives are eliminated through the kidneys.

Ascorbic acid, at an intake of 30 to 180 mg daily about 70 – 90 % is absorbed from the lumen of small intestine, regarding metabolism, it is oxidized to dehydroascorbic acid which can be either reduced back to ascorbic acid or hydrolyzed to diketogulonate & other metabolites, and the principal route of excretion of ascorbic acid & its metabolites is via kidney.

6-Pharmaceutical particulars:
List of excipients:
Maize starch, Microcrystalline cellulose (Avicel pH 102), Methyl cellulose, Croscarmellose sodium, Disodium edetate, Sodium metabisulphite, Purified talc, Colloidal anhydrous silica, Magnesium stearate, Opadry AMB yellow 80W22569

Incompatibilities:
- Not applicable

Shelf life:
3 years

Special precautions for storage:
- Store in cool dry place, below 30°C.
- Keep out of reach of children.

6.5 Nature and contents of container:
Carton box containing 3 blisters each containing 10 tablets & insert leaflet.

6.6 Special precautions for disposal:
No special requirements

7-Market authorization holder:
Eva Pharma for Pharmaceuticals & Medical Appliances – Egypt

8. Marketing authorization number(s)
HNM.0.10.1.1.6

9. Date of first authorization/renewal of the authorization
1/6/2006

10. Date of revision of the text
04/2015