PACKAGE INSERT TEMPLATE FOR GLUCOSAMINE TABLET/CAPSULE SACHET/GRANULES FOR ORAL SOLUTION

Brand or Product Name

[Product name] Tablet ….mg
[Product name] Capsule …mg
[Product name] Sachet/Granules for Oral Solution …mg

Name and Strength of Active Substance(s)

Glucosamine sulphate potassium chloride …mg equivalent to… mg glucosamine sulphate
Glucosamine sulphate sodium chloride …mg equivalent …mg glucosamine sulphate
Glucosamine hydrochloride …mg equivalent to …mg glucosamine

Product Description

[Visual description of the appearance of the product (eg colour, odour, superficial markings, ident, coated/uncoated, size of tablet/capsule)]
eg White, circular flat beveled edge tablets marked '500' on one side
White, crystalline, odourless powder

Pharmacodynamics

Glucosamine is a natural substance found in chitin, mucoproteins, and mucopolysaccharides. It is involved in the manufacture of glycosaminoglycan, which forms cartilage tissue in the body; glucosamine is also present in tendons and ligaments. Glucosamine must be synthesised by the body but the ability to do this declines with age. Glucosamine and its salts have therefore been advocated in the treatment of rheumatic disorders including osteoarthritis.

Glucosamine also acts to improve the viscosity of synovial fluid by increasing synovial fluid production, thereby providing lubricant activity.

Pharmacokinetics

Absorption
After oral administration, bioavailability is low due to first-pass hepatic metabolism~26%
The gastrointestinal absorption is close to 90%

Distribution
Glucosamine is not protein-bound, but rather incorporates into plasma proteins (primarily globulins)
Volume of Distribution: 2.5 Liters

Metabolism
-Liver, extensive
The first-pass effect in the liver in which more than 70% of glucosamine is metabolized.

Excretion
Renal Excretion, 10%
Feces, 11%
Part of a dose of glucosamine sulfate is eliminated as carbon dioxide via expired air

Indication

Adjuvant therapy for osteoarthritis

Recommended Dosage

Adults

1500 milligrams daily, single dose or in 3 divided doses

Dosing also may be based on severity:

a) Light or moderate osteoarthritis symptoms:
1 capsule taken twice daily (1000mg) for at least 6 weeks or according to medical prescription.

b) Severe osteoarthritis symptoms:
Initially treatment of 1 capsule three times daily (1500mg) is recommended during a period of at least 8 weeks-12 weeks.

c) Follow-up therapy:
Maintenance therapy should be followed for 3 -4 months (as according to medical prescription) by administration of 1 capsule taken twice daily (1000mg).
The treatment of osteoarthritis should be repeated every other 6 months or less (according to medical prescription)

Children

Safety and effectiveness have not been established in children

Mode of Administration
Oral

Contraindications

Hypersensitivity to glucosamine or to any of the excipients
As the active ingredient is obtained from seafood (shellfish), the product should not be given to patients who are allergic to shellfish

Warnings and Precautions

Glucosamine treats the underlying cause of osteoarthritis and the therapeutic effect can only be seen after 2-3 weeks. Therefore, it is advisable to take an analgesic/anti-inflammatory drug if required during the first 2-3 weeks of therapy with glucosamine.

Administration during the first three months of pregnancy must be avoided.

Safety and effectiveness have not been established in children therefore children, should avoid using glucosamine

The administration in patients with severe hepatic or renal insufficiency should be made under medical supervision.

Derived from Seafood, therefore should not be given to patients who are allergic to shellfish

A doctor should be consulted in order to exclude the presence of other joint conditions/disesases for which an alternative treatment should be considered

Effects on Ability to Drive and Use Machines
No effects on the ability to drive or to operate machines are expected.

Interactions with Other Medicaments

Effects on glucose metabolism & antidiabetic agents:

It has been hypothesized that glucosamine may impair insulin secretion through competitive inhibition of glucokinase in pancreatic beta cells and/or alteration of peripheral glucose uptake.

Glucosamine may increase insulin resistance and consequently affect glucose tolerance.

It may reduce antidiabetic agent effectiveness eg when used with these antidiabetic agent :

Acarbose**,** Acetohexamide, Chlorpropamide**,** Glipizidede, Glyburide, Metformin, Miglitol, Pioglitazone, Repaglinide, Rosiglitazone, Glimepiride , Tolbutamide, Troglitazone,

Glucosamine is likely safe in patients with well-controlled diabetes (HbA1c less than 6.5%) taking one or two oral antidiabetic medications or controlled by diet only. In patients with higher HbA1c levels or those taking insulin, monitor blood glucose levels closely/more frequently

Reduced effectiveness when used with glucosamine: Doxorubicin , Etoposide , Teniposide

Warfarin

- elevations of International Normalized Ratio serum values and potentiation of anticoagulant effects

-If concomitant therapy is necessary, the patient's INR should be more closely monitored

Statement on Usage During Pregnancy and Lactation

Available evidence is inconclusive or inadequate for use in pregnant or lactating mothers. Until more information is available, this product should only be used under medical supervision in pregnancy and lactating mothers if the potential benefit to the mother justifies the potential risk to the fetus.

Administration during the first 3 months of pregnancy must be avoided.

Adverse Effects / Undesirable Effects

[Specific package insert requirement for glucosamine]

Cardiovascular:

Peripheral oedema, tachycardia were reported in a few patients following larger clinical trials investigating oral administration in osteoarthritis. Causal relationship has not been established.

Central nervous system:

Drowsiness, headache, insomnia have been observed rarely during therapy (less than 1%).

Gastrointestinal:

Nausea, vomiting, diarrhoea, dyspepsia or epigastric pain, constipation, heartburn and anorexia have been described rarely during oral therapy with glucosamine.

Skin:

Skin reactions such as erythema and pruritus have been reported with therapeutic administration of glucosamine.

Overdose and Treatment

No cases of accidental or intentional overdose are known. The animal acute and chronic toxicological studies indicate that toxic effects and symptoms of toxicity are not likely to occur, even after high overdoses.

Storage Conditions
[eg Store below…°C]

Dosage Forms and Packaging Available
[Packaging type & pack size eg HDPE bottle of 30s/box etc]

Name and Address of Manufacturer
[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder
[Name & full address of marketing authorization holder]

Date of Revision of Package Insert
[day/month/year]