GLUCOSAMINE SULPHATE 2KCl 1500mg Tablet

1. **Product Description**
   One tablet contains Glucosamine Sulphate 2KCl 1500mg

   White to off white/yellow tablets with yellow speckles.

2. **Pharmacodynamics/ Pharmacokinetics**
   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.

   The pharmacokinetics of glucosamine sulfate (CAS 29031-19-4) was investigated in 6 healthy male volunteers (2 per administration route) using 14C uniformly labelled glucosamine sulfate and administering it in single dose by intravenous (I.V.), intramuscular (I.M.) or oral route. The results show that after I.V. administration the radioactivity due to glucosamine appears in plasma and is rapidly eliminated, with an initial time of 0.28 h. 1-2 h after administration the radioactivity due to glucosamine disappears almost completely and is replaced by a radioactivity originating from plasma proteins, in which glucosamine or its metabolites are incorporated. This radioactivity reaches a peak after 8-10 h and then declines with a time of 70h. About 28% of the administered radioactivity is recovered in the urine of the 120h following the administration and less than 1% is recovered in the feces. After I.M. administration similar pharmacokinetic patterns are observed. After oral administration a proportion close to 90% of glucosamine sulfate is absorbed. Free glucosamine is not detectable in plasma. The radioactivity incorporated in the plasma proteins follows pharmacokinetic patterns which are similar to those after I.V. or I.M. administration, but its concentration in plasma is about 5 times smaller than that after parenteral administration. The AUC after oral administration is 26% of that after I.V. or I.M. administration. The smaller plasma levels of radioactivity after oral administration are probably due to a first pass effect in the liver which metabolizes notable proportion of glucosamine into smaller molecules and ultimately to CO2, water and urea. The results confirm previous investigations in rats and dogs showing also that in man glucosamine sulfate is a prodrug for glucosamine that is well absorbed after oral administration and that, after I.V., I.M. or oral administration, diffuses into several tissues, including bones and articular cartilages.

3. **Indication**
   As adjuvant therapy for osteoarthritis.

4. **Recommended dosage**
   Adults: One tablet once daily with food.

5. **Route of administration**
   For oral administration only.

6. **Contraindications**
   Hypersensitivity to glucosamine sulphate. Derived from seafood. If you are allergic to seafood, consult your doctor or pharmacist.

7. **Warning and Precautions**
   Do not exceed the stated dose unless instructed by a qualified health professional.
   Glucosamine is a causal therapy, and the therapeutic effect can only be seen after approximately 1 week from the beginning. Therefore, in case of intense pains, it is advisable to take an anti-inflammatory drug in addition during the first days of treatment with glucosamine.

8. **Interaction with other medicaments**
   Glucosamine might increase insulin resistance or decrease insulin production resulting in elevated blood glucose levels. This increase in blood glucose may require increases in administered insulin and/or hypoglycemic agents such as sulfonylureas and metformin. Therefore, glucosamine should be used only in diabetic patients who exhibit tight blood glucose control (HbA1c less than 6.5%).

9. **Usage during pregnancy and lactation**
   Pregnancy and lactation should be used only under medical control. Administration during the first three months of pregnancy must be avoided.

10. **Effects on ability to drive and use machine**
    Glucosamine is not known to have any effects on driving ability or the operation of machinery.

    Some individuals may experience gastrointestinal discomfort, such as nausea, heartburn and diarrhoea when taking glucosamine. If these symptoms occur, they could potentially affect someone's ability to concentrate or operate machinery safely.

11. **Adverse effects / Undesirable effects**
    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.

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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.

12. Overdose and treatment
Symptoms may include mild heartburn and epigastric pain, nausea and abdominal pain. In the event of an accidental overdose, consult a qualified health professional.

13. Storage conditions
Store in a dry place, below 30°C. Protect from light and moisture.

14. Packaging available
30 tablets (15's x 2 blisters)

15. Name and address of manufacturer
Quest Vitamins Middle East FZE
Plot No. S20708A, Street 230
Building 13, Jebel Ali Free Zone
Dubai 17836
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16. Date of Revision: August 2024