DONNA Forte Capsule 500mg

DESCRIPTION: A size '0' capsule with black cap marked 'DONNA' and red body marked '500' with off white to beige fill.

COMPOSITION: Each capsule contains Glucosamine Sulphate Sodium Chloride equivalent to Glucosamine Sulphate 500mg.
Gelatin for hard capsule: Bovine source.

ROUTE OF ADMINISTRATION: Oral.

PHARMACODYNAMICS:
(a) Arthrotrophic metabolic activity by stimulating the anabolic metabolism of osteo-cartilagineous tissues, through:
- stimulation of the biosynthesis of the mucopolysaccharides (which are the essential components of the cartilage ground-substance) and of the bone mesenchymal tissues in general.

(b) Lubricant activity through:
- improvement of synovial fluid viscosity.
- increase of synovial fluid production.

Glucosamine is recommended for the management of degenerative osteoarticular disease, eg. arthrosis and osteoarthritis both subacute and chronic with disappearance or reduction of articular pains, improvement of articular function, and inhibition or regression of the degenerative process.

PHARMACOKINETICS:
Pharmacokinetics of glucosamine in man: The pharmacokinetics of glucosamine sulphate was investigated in 6 healthy male volunteers (2 per administration route) using ^{14}C uniformly labeled glucosamine sulphate and administering it in single dose by intravenous (i.v), intramuscular (i.m) or oral route. After oral administration a proportion close to 90% of glucosamine sulphate is absorbed. Free glucosamine is not detectable in plasma during this study, because of the high detection limit of the method use. However, levels of Glucosamine Sulphate incorporated in plasma proteins reached a peak after 8-10 hours and then declined, exhibiting a half-life of 68 hours. Following oral administration, 10% was excreted via the urine, whereas 11.3% was found in the faeces.
The radioactivity incorporated in the plasma proteins follows pharmacokinetics 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 plasma levels of radioactivity investigations in rats and dogs showing that also in man glucosamine sulphate is prodrug for glucosamine that is well absorbed after oral administration and that diffuses into several tissues, including bones and articular cartilages.

INDICATION: As an adjuvant therapy for osteoarthritis.

RECOMMENDED DOSAGE:
Light or Moderate Arthrosic Symptoms: 1 cap twice daily for at least 6 weeks.
Severe Arthrosic Symptoms: Initial therapy: 1 cap 3 times a day is recommended during a period of at least 8 weeks.
Follow-up Therapy: Maintenance therapy should be followed for 3-4 months by administration of 1 cap twice daily.
Long-term treatment: The treatment should be repeated every other 6 months or less as required.
Glucosamine sulphate is a causal therapy and the therapeutic effect can 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. Capsules should be taken 15 min before each meal.

CONTRAINDICATIONS: Contraindicated in patients hypersensitive to glucosamine and allergic to shellfish.

WARNING & PRECAUTIONS:
Glucosamine may increase insulin resistance. Those with type 2 diabetes and those who are overweight and have problems with glucose tolerance should have their blood sugars carefully monitored if they consume glucosamine. Because of insufficient data, children, pregnant women and lactating mothers should avoid using glucosamine.
Children: The medical literature has not reported any adverse effects related to glucosamine use in children. Since young children may have undiagnosed allergies or medical conditions, glucosamine should not be used in children under 12 years of age unless recommended by a physician.
DERIVED FROM SEAFOOD.

INTERACTION WITH OTHER MEDICATIONS:
An increased in International Normalised Ratio (INR) was noted when glucosamine was administered to patient who is treated with warfarin.
Glucosamine may increase the anti-inflammatory activity of NSAIDS such as ibuprofen. This interaction may result in the need for lower doses of these medications.

USE IN PREGNANCY & LACTATION:
To date, there are no reported adverse effects related to fetal development during pregnancy or to infants who are breast-fed. However, it is recommended to consult healthcare practitioner if glucosamine is taken while pregnant or breastfeeding.

SIDE EFFECTS:
The most frequently observed adverse events occurring after glucosamine treatment were mild digestive problems, including epigastric tenderness, heartburn, diarrhea and nausea.
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, diarrhea, 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.

SYMPTOMS AND TREATMENT OF OVERDOSE: None available.

STORAGE CONDITION: Store below 30°C. Protect from moisture and heat. Keep out of reach of children. *Jauhi daripada kanak-kanak.*

PACK SIZE: In box of 10x9 blisters, 10x6 blisters, 10x3 blisters and 10x10 blisters

SHELF LIFE: Please refer to outer package

PRODUCT REGISTRATION HOLDER:
DUOPHARMA MARKETING SDN. BHD.
Lot No. 2,4,6,8 & 10, Jalan P/7, Section 13, Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor, Malaysia.

MANUFACTURER:
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