GUTRIL-S
GLUCOSAMINE SULPHATE
POWDER FOR ORAL SOLUTION

Active Ingredient:
Each sachet contains:
Glucosamine Sulphate Sodium Chloride 1884mg (equivalent to Glucosamine Sulphate 1500mg)
Derived from seafood.

Description: White or almost white crystalline powder is filled in aluminium sachet. The solution is clear and colourless with salty taste after dissolved the powder in water.

Pharmacodynamic:
Glucosamine which can stimulate the production of cartilage- building compounds, restore damaged cells of cartilage tissue and has some anti-inflammatory abilities.

Pharmacokinetic:
Glucosamine is a relatively small molecule which can be easily dissolved in water and soluble in hydrophilic organic solvents. The distribution volume is approximately 5 litres and the half- life after intravenous administration is approximately 2 hours. Approximately 38% of an intravenous dose is excreted in the urine as unchanged substance.

Indication: Used as adjuvant therapy for osteoarthritis.

Recommended Dose:
1 sachet daily. Dissolve the powder in a glass of water (250ml) and drink it.

Glucosamine is not used for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after some weeks of treatment or sometimes even longer. If your symptoms do not get better after 2- 3 months, you should speak to your doctor or pharmacist as you may need to consider other treatment.

Route of Administration: Oral

Contraindication:
Hypersensitivity to glucosamine sulphate or patients who are allergic to shellfish.

Glucosamine sulphate should not be used in patients taking warfarin (or other coumarin anticoagulants) as increased effect during concomitant treatment with glucosamine has been reported.

Glucosamine sulphate should not be used in patients with impaired renal and/ or liver function, as no dose recommendations can be given since no studies have been performed.

Patients taking oral tetracycline should not take glucosamine at the same time, as concurrent treatment with glucosamine may increase the absorption and serum concentrations of tetracyclines.

Warning & Precautions:
A doctor must be consulted to rule out the presence of joint diseases for which other treatment should be considered.

A doctor must be consulted if this medicine intended for long term use.

As the risk of diabetogenic effects is unknown and until further evidence becomes available, caution should be exercised in patients with diabetes or a predisposition for diabetes.

Therefore, in patients with impaired glucose tolerance, pre-diabetics and diagnosed diabetics (Type I and II), monitoring of the blood glucose levels should be increased, as deemed necessary, before start of treatment, periodically during treatment and at the end of the treatment, as determined by the primary Healthcare Professional.

Where relevant, monitoring of insulin requirements is also recommended before start of treatment, periodically during treatment and at the end of the treatment under medical supervision.

In patients with a known risk factor for cardiovascular disease, monitoring of the blood lipid levels is recommended during treatment with Glucosamine sulphate since hypercholesterolemia has been observed in a few patients treated with glucosamine. The results should be a factor in determining whether treatment is continued after 2-3 months.

A report on exacerbated asthma symptoms triggered after initiation of glucosamine therapy has been described (symptoms resolved after withdrawal of glucosamine). Asthmatic patients starting on glucosamine should therefore be aware of potential worsening of symptoms.

Effect on Ability to Drive and Use Machines: Not known

Interactions with Other Medicaments:
Hypoglycaemic agents
Close monitoring of blood sugar levels is recommended for diabetics on hypoglycaemic agents.

Warfarin
There are limited data on possible drug interactions with glucosamine, but increments in the INR parameter have been reported with oral vitamin K antagonists. Patients treated with oral vitamin K antagonists should therefore be closely monitored at the time of initiation or termination of glucosamine therapy.

Tetracyclines
Concurrent treatment with glucosamine may increase the absorption and serum concentration of tetracyclines, but the clinical relevance of this interaction is probably limited. If the patient is taking oral tetracycline they should not take glucosamine at the same time.

Pregnancy & Lactation:
Pregnancy
There are no adequate data from the use of glucosamine in pregnant women. From animal studies only insufficient data are available. Glucosamine sulphate should not be used during pregnancy.

Breastfeeding
There are no data available on the excretion of glucosamine into human milk. The use of glucosamine sulphate during breastfeeding is therefore not recommended as there is no data on the safety for the newborn.

Side 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.

- 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.

Symptoms & Treatment of Overdose:
Signs and symptoms of accidental or intentional overdose might include headache, dizziness, disorientation, arthralgia, nausea, vomiting, diarrhea or constipation.
In case of overdose, treatment with glucosamine should be discontinued.

Storage Condition:
Store below 30°C.
Keep out of reach of children.
Jauhkan daripada capaian kanak- kanak.

Shelf Life: 3 years

Packing: 30 sachets x 1884mg per sachet

Distributed by Product Registration Holder:
Janipro Sdn. Bhd. (838162-X)
42 Jalan Seksyen 1/21, Taman Kajang Utama,
43000 Hulu Langat, Selangor, Malaysia.

Manufacturer:
Syarikat Wen Ken Drug Sdn. Bhd.
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Date of Revision: Feb 2023