(For the use only of a registered Medical Practitioner or a Hospital or a Laboratory)

Glutathione for Injection 2000mg

AMERICAN

GLUTACAN 600/1200/2000

Injection

Single Dose Vial
For IM/IV use only

Composition :

Each Lyophilized vial Contains :

Glutathione USP	2000 mg
Excipients	q.s.

DESCRIPTION

Glutathione is a physiologic tripeptide – a chain of three amino acids – cysteine, glycine and glutamic acid. It is consumed in the detoxification of electrophilic metabolites. It is a very e□cient free radical scavenger and protects cells from the noxious e□ects of reactive oxygen compound. Glutathione for Injection is available as sterile, white lyophilized powder for injection.

PHARMACOLOGY

Peak plasma concentration is reached in about 5 hours after intramuscular injection, and t½ is about 24 hours. Data shows that after injected with S-GSH, S-GSH is well distributed in all organs within a short period of time, with higher concentration in liver, kidney and spleen than in other organs. While the distribution (measured in unit body weight) of S-GSH in heart, skeletal muscle and brain is not as high as in other organs, the excretion of S-GSH via these organs is slower. Seven days after the injection, 24±4.2% of the S-GSH is excreted in the urine. After intravenous infusion of 2 g/m² of glutathione, the plasma concentration of glutathione increased from an average of 6.9 mmol/l to a peak plasma concentration of approximately 444 mmol/l. The volume of distribution was approximately 15 l, plasma half life was approximately 10 minutes, and average clearance rate was 850 ml/min/m². 90 minutes after the first infusion, urinary excretion of glutathione and cysteine increased by 300% and 10% respectively.

CONTRAINDICATIONS

It is contraindicated in patients who show hypersensitivity to Glutathione.

PRECAUTIONS

Administer Glutathione Injection under the supervision of a doctor. Make sure that the drug is completely dissolved before injection and that the solution is clear and colorless; the constituted drug solution should not be kept for more than 2 hours at room temperature (up to 25°C) and for more than 8 hours in physiologic saline at 0–5°C. Keep out of reach of children.

If unusual symptoms such as eruption, pale face, blood pressure drop, or di□culty in breathing occur during therapy, discontinue the drug administration immediately. Intramuscular injection is allowed only when this route of administration is needed. Avoid injecting at the same site repeatedly. The products for parenteral use should be visually inspected before administration, in order to detect the presence of particles or of an abnormal color. Do not use in case of turbidity or precipitates.

PREGNANCY AND LACTATION

The available evidence shows that glutathione, being a substance physiologically present in cells, does not cause side e□ects in women during pregnancy and lactation. Nevertheless, as with all drugs, glutathione should only be administered to pregnant or lactating women if the benefits outweigh the risks.

PEDIATRIC USE

The drug should be used with caution in neonates, premature infants and children especially when it is administered by intramuscular injection.

INDICATIONS

For the treatment of alcoholic liver disease, alcoholic fatty liver, alcoholic liver fibrosis, alcoholic liver cirrhosis and alcoholic hepatitis. There is evidence that glutathione homeostasis and alterations in glutathione-dependent enzyme activities could result in induction and progression of neurodegenerative diseases. Glutathione injection is also indicated in reducing neurotoxicity of oxaliplatin chemotherapy. Empirically glutathione injections have been used for lightening skin tone.

DOSAGE AND ADMINISTRATION

Dosage: The dose of Glutathione injection is dependent on severity. The usual dose is 600 mg / 1200 mg / 2000 mg daily by IM Injection or IV Infusion.

ADMINISTRATION

For intramuscular injection or bolus i.v. injection, dissolve the vial contents with the ampoule solvent. For intravenous infusion, the solution obtained as above mentioned must be further diluted to 250 ml or 500 ml with normal saline or 5% of glucose solution. The reconstituted solution must be used immediately after preparation. Vitamin C 500mg/5ml should also be concurrently administered.

ADVERSE REACTIONS

After intramuscular administration of Glutathione, rare instances of skin rash have been reported which have disappeared after discontinuation of treatment. Mild pain at injection site has also been reported. As is the case with all intravenous infusions, febrile reactions, infections at site of injection, venous thrombosis and phlebitis and extravasation may occur.

GERIATRIC USE

For the elderly patients, appropriate dose reduction and strict monitoring is required during therapy.

DRUG INTERACTIONS

Vitamin K, vitamin B12, calcium pantothenate and antihistamines can affect the bioavailability of glutathione.

OVERDOSAGE

No adverse events resulting from overdosage have been reported.

Storage :Store in a cool, dry & dark place.
Protect from light and moisture. Do not freeze.

Improper storage condition may deteriorate the product quality.

Keep the medicine out of reach of children.

Shelf Life: As printed on the carton

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