

To be sold by retail on the prescription of Registered Medical Practitioner only.

## Glutathione for injection 600 mg/vial

**Glutarey™**

Lyophilized

### Composition:

Each vial contains  
Glutathione BP .....600 mg  
Excipients ..... q.s.

### DESCRIPTION :

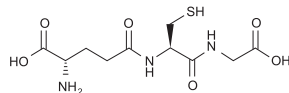
Glutathione is a physiological tripeptide- a chain of three amino acid- cysteine, glycine and glutamic acid. It is used for the detoxification of electrophilic metabolites. It is a very efficient free radical scavenger, preventing damage to important cellular components caused by reactive oxygen species such as free radicals and peroxides. Glutarey injection is available as sterile, white lyophilized powder for injection.

### Chemical Name :

(2S)-2-Amino-4-[1-(carboxymethyl)carbamoyl-(2R)-2-sulfanylethylcarbamoyl] butanoic acid

**Molecular Formula :** C<sub>10</sub>H<sub>17</sub>NaO<sub>6</sub>S

**Molecular Weight:** 307.32 g/mol



Structure of Glutathione

### CLINICAL PHARMACOLOGY :

#### Pharmacological Action

Glutathione is an extremely important cell protectant which directly quenches reactive hydroxyl free radicals, other oxygen-centered free radicals, and radical centers on DNA and other biomolecules. It is an essential cofactor for many enzymes which require thiol-reducing equivalents, and helps to keep redox-sensitive active sites on enzymes in the necessary reduced state. Higher-order thiol cell systems like metallothioneins, thioredoxins, and other redox regulator proteins are ultimately regulated by reduced form of Glutathione (GSH) levels and the ratio of GSH/GSSG (oxidized GSH).

GSH/GSSG balance is crucial for homeostasis, stabilizing the cellular biomolecular spectrum, and facilitating cellular performance and survival. GSH and its metabolites also interface with energetics and neurotransmitter syntheses, through several prominent metabolic pathways. GSH availability down-regulates the pro-inflammatory potential of leukotrienes and other eicosanoids. Recently discovered S-nitroso metabolites, generated in-vivo from GSH and NO (nitric oxide) further diversify GSH's impact on metabolism.

#### Pharmacokinetics

After intravenous infusion of 2 g/m' of Glutathione, the plasma concentration increases from an average of 6.9 mmol/L to a peak plasma concentration of approximately 444 mmol/L. The volume of distribution is approximately 15 L, plasma half life is approximately 10 minutes, and average clearance rate is 850 ml/minim'. After 90 minutes of the first infusion, urinary excretion of Glutathione and cysteine increases by 300% and 10% respectively.

In addition, after high-dosage intravenous administration (50 mg/kg of body weight), Glutathione shows following pharmacokinetic parameters in healthy volunteers.

Parameters	Values
C <sub>max</sub>	1205.8 μM
AUC	12427 μM.min
t <sub>1/2</sub>	10.9 min
V <sub>d</sub>	0.152 L/kg

After intramuscular injection, Glutathione reaches peak plasma concentration within 5 hours. Data shows that, Glutathione is well distributed in all the 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 GSH in heart skeletal muscle and brain is not as high as in other organs, the excretion of GSH via these organs is slower. Seven days after the injection, 24±4.2% of the GSH is excreted in the urine.

### INDICATIONS & USAGE

Glutarey injection is indicated for the treatment of

- Alcoholic fatty liver
- Alcoholic liver fibrosis
- Alcoholic liver cirrhosis
- Alcoholic hepatitis

### DOSAGE & ADMINISTRATION :

#### Dosage

The dose of Glutarey injection is dependent on severity of the disease, in mild to moderate disease- 300 mg to 600 mg daily by slow intramuscular or intravenous injection.

#### Administration

**Intravenous drip:** Dissolve with 5 ml sterile water for injections IP; the solution is further diluted into 250 ml or 500 ml with normal saline or 5% glucose solution for intravenous infusion respectively.

**Intramuscular injection :** Dissolve with 5 ml sterile water for injections IP. Inject the solution intramuscularly, preferable in gluteal region.

### 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 or phlebitis and extravasation may occur.

### CONTRAINDICATIONS :

Glutarey injection is contraindicated in the patients who show hypersensitivity to reduced Glutathione.

### PRECAUTIONS :

- Administer Glutarey injection under the supervision of a doctor.
- If unusual symptoms such as eruption, pale face, blood pressure drop, or difficulty in breathing occur during therapy, discontinue the drug administration immediately.
- Administer Glutarey injection intramuscularly only when the need arises. 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.
- Use immediately after reconstitution.

### USE IN SPECIAL POPULATION :

#### Pregnancy & Lactation

Glutarey injection should not be administered to a pregnant and lactating woman unless clinical benefit outweighs the risks.

#### Pediatric

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

#### Geriatric

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 have been reported after Glutathione intravenous infusion up to 50 mg/kg dosage.

No specific antidote is available for the treatment of Glutathione overdosage.

Symptomatic treatment should be provided.

### STORAGE:

Store below 25°C. Protect from light.

Keep out of reach of children.

After reconstitution, do not use in case any foreign particulate matter is observed inside the vial.

### PRESENTATION

Box containing one Vial of 600 mg of Glutarey with 5 mL of Sterile water for injections.

Manufactured in India by:

**Caplin Point Laboratories Ltd.,**  
R.S. No.: 85/3, Suthukeny Village,  
Mannadipet Commune Panchayat,  
Puducherry – 605 502.

**GALENGEN**

Marketed by : **Galengen Lifesciences Pvt. Ltd.,**  
First floor, South Wing,  
No.51,11<sup>th</sup> Cross Street, 9<sup>th</sup> Main Road,  
Dhandeeswaram Nagar, Velachery, Chennai - 600 042.

TM-Trade Mark

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