50 X 135 MM

mm

Front

Back

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

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Glutathione for Injection 600mg

GT-600™
Injection

COMPOSITION :
Each vial contains :
Glutathione BP.....600mg
Excipients.....qs

Single Dose Vial
Lyophilized Powder

QUALITATIVE AND QUANTITATIVE COMPOSITION
1 vial contains
Active principle: Glutathione
equal to glutathione 600 mg
PHARMACEUTICAL FORM
Powder and solvent for solution for injection.
CLINICAL PARTICULARS
Therapeutic indications
For the treatment of alcoholic liver diseases like alcoholic fatty liver, alcoholic liver fibrosis, alcoholic liver cirrhosis, and hepatitis
Posology and method of administration
Posology
1-2 vials a day by intramuscular injection, by slow intravenous injection, or by intravenous infusion.
The dose depends on patient's age, body weight and clinical conditions and on the dose and posology of the chemotherapeutic agent.
Pediatric population
The safety and efficacy of this medicinal product in children have not been determined.
Method of administration
The product should be administered 15-30 minutes prior to the beginning of chemotherapy.
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 in at least 20 ml of water for injectables.
The reconstituted solution must be used immediately after preparation.
Contraindications
Hypersensitivity to the active principle or to any of the excipients listed in section 6.1.
Special warnings and precautions for use
Use immediately after opening the container. The reconstituted solution must be clear, colorless and free from visible particles and must be used for a single, uninterrupted administration. Any remaining solution should be discarded.
Interaction with other medicinal products and other forms of interaction
There are no reports of pharmacological interaction with glutathione.
Fertility, pregnancy and lactation
Pregnancy
There are no available data on possible damage caused by the medicinal product, if administered during pregnancy.
Lactation
There are no available data on possible damage caused by the medicinal product, if administered to nursing women.
Fertility
There are no available data on possible damage to fertility caused by the medicinal product.
Therefore, the medicinal product must not be used during pregnancy and lactation, unless strictly necessary and only after careful evaluation of the benefit/risk ratio.
Effects on ability to drive and use machines
The medicinal product does not affect the ability to drive and use machines, or its influence on such activities is negligible.
Undesirable effects
The undesirable effects of glutathione, classified by system organ class according to MedDRA, are reported hereunder.
There are not sufficient available data to establish the frequency of the listed individual effects.
Gastrointestinal disorders
Nausea, vomiting.
Immune system disorders
Hypersensitivity reactions, skin rash, urticaria.
Nervous system disorders
Headache.

General disorders and administration site conditions
Febrile reactions, pain and infection at the infusion site, venous thrombosis, venous phlebitis extending beyond the infusion site, extravasation and possible extravasal diffusion.

Reporting of suspect adverse reactions
Reporting of suspect adverse reactions occurring after the marketing authorization of the medicinal product is important, as it allows the continuous monitoring of the drug risk/benefit ratio. Health operators are therefore requested to report any suspect adverse reaction to the national health system through the website www.agenziafarmaco.gov.it/it/responsabili.
Overdose
No overdose cases have ever been reported.
If necessary, symptomatic treatment should be considered.
PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: antidote, ATC code: V03AB32
Glutathione (GSH) is a physiological tripeptide made of glutamic acid, cysteine and glycine, largely available in nature and found in the cell cytosol.

Mechanism of Action
Glutathione participates in a wide range of biological processes and plays an important role in detoxification reactions, protecting the cells from the harmful effects of xenobiotic agents, as well as environmental and intracellular oxidants (free radicals, reactive oxygen intermediates). Preclinical and clinical studies have shown the protective role of glutathione in many pathological conditions that cause cell damage. Besides, it has been observed that several chemotherapeutic agents reduce tissue and intracellular levels of endogenous GSH, thus worsening the condition of oxidative stress caused by the tumor.
The sulfhydryl group in the cysteine portion of glutathione, which is strongly nucleophilic and therefore a primary target for electrophilic attack by chemical substances and by their reactive metabolites, enhances such protective action, by shielding essential nucleophilic sites that, if attacked, would start a cell damaging process. Glutathione reacts with a great variety of oxidized organic metabolites, originating less toxic conjugates that can be more easily metabolized and excreted as mercapturic acids. Besides, glutathione exerts a protective effect on the SH-enzymes that are responsible for important biochemical cell functions.

In particular, the secondary toxic effects of many drugs, of malnutrition, of several diseases and wrong dietary choices lower the hepatic levels of glutathione. In particular, the neurotoxic effects induced by chemotherapeutic agents such as cisplatin and its derivates appear to be due to the accumulation of platinum in the peripheral nervous system and in particular in the posterior root ganglions. In the case of oxaliplatin, platinum accumulation appears to be due to slower elimination, rather than greater accumulation. This suggests that use of such agents as glutathione can prevent the initial accumulation of platinum in the posterior root ganglions. Several clinical studies have confirmed this effect. The studies show that glutathione infusion prior to the administration of the antiblastic agent to patients with ovarian cancer, stomach cancer and colorectal cancer provides effective protection against cisplatin-and oxaliplatin -induced nephro - and neurotoxicity, thus allowing to reach, if necessary, higher cumulative doses of the antiblastic agent.
Pediatric population
The safety and efficacy of this medicinal product in children have not been determined.
Pharmacokinetic properties
Distribution
Following intravenous administration, glutathione is primarily found in the red blood cells, whereas at plasmatic level it is rapidly decomposed by gamma-glutamyl-transpeptidase and by gamma-glutamyl-cyclotransferase. Therefore, the plasma levels of reduced glutathione, even after administration of high doses, are negligible (plasma peak of about 1 nmol/ml 5 minutes after administration of 600 mg i.v.).
Following the intravenous infusion of 2 g/m2 glutathione in healthy volunteers, total plasmatic concentration of glutathione
increased from 17.5 ± 13.4 mmol/l (mean ± SD) to 823 ± 326 mmol/l. The calculated distribution volume of exogenous
glutathione is 176 ± 107 ml/kg, with a plasmatic half-life of 14.1 ± 9.2 minutes.
After administration, glutathione blood levels gradually decrease almost to baseline levels in about 60 minutes.
Biotransformation
The plasmatic concentration of the metabolite cysteine increased from 8.9 ± 3.5 mmol/l to 114 ± 45 mmol/l after the infusion. In spite of cysteine increase, total plasma concentration of total cysteine, cysteine and mixed disulfides decreased, showing an increased passage of cysteine in the cells.
Elimination
Urinary excretion of glutathione and cyst(e)ine showed a 300% and 10% increase, respectively, in the 90 minutes after the infusion.
These data indicate that the intravenous administration of glutathione distinctly increases the concentration of sulfhydryl compounds in the urinary tract and, consequently, the cellular availability of cysteine. The high cysteine concentration in the cells explains its protective effect against xenobiotics, which directly or indirectly translates into increased glutathione biosynthesis.
Preclinical safety data
Acute toxicity
By intravenous administration: in rats and mice, doses of up to 5000 mg/Kg glutathione sodium, administered by slow intravenous infusion (5 ml/minute), do not cause death. In rabbits, 3000 mg/Kg doses are well tolerated. By intraperitoneal administration: in mice and rats, 7500 mg/Kg doses do not cause death.
Subacute toxicity
By intravenous administration: 500 mg/kg/day and 100 mg/kg/day doses for 28 days have caused no particular symptoms in
rabbits.
Chronic toxicity
Intraperitoneal doses of 43.86 and 129 mg/Kg did not produce any harmful effects either on the biochemical values or on the various body systems of rats.
Dogs treated intravenously for 90 days at doses of 86 and 129 mg/kg/day did not present with any particular symptoms,
biochemical parameter changes or histomorphological changes in the main systems and organs at the end of treatment.
Teratogenicity
In tests carried out on Wistar rats and New Zealand rabbits with 86 mg/kg/day doses, glutathione did not affect the reproductive function of the adult animals, or the development and feeding of the litter.
Local tolerance
Intravenous and intraperitoneal administration and the local application of the product in the conjunctival sac (as eye drops) did not cause any irritation, even with chronic administration.
PHARMACEUTICAL PARTICULARS
List of solvent for reconstitution
The solvent ampoule contains water for injection & Vitamin C 5 ml
Vitamin c is a good soluble agent.
Vitamin c & Glutathione chemical structure is same so its absorbance in body is easy and effective..Vitamin c increases efficiency of glutathione injection in comparison of wfi. for a weak body it works as a booster who enhances energy of body.
Use one of the above as per your choice from Vitamic C and Wfi for dissolve.
Incompatibilities
None reported.
For lack of incompatibility studies, the medicinal product must not be admixed to other products.
Shelf-life
2 years.
Storage: Store below 25°C away direct sunlight, heat, and moisture.

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