FDP MEDLAC

POWDER FOR INJECTION

COMPOSITION

Each vial contains: 5.0g of Fructose 1,6-Diphosphate Trisodium hydrate ($3H_2O$) corresponding to 3.75g Fructose 1,6-Diphosphoric acid.
Each solvent vial contains: 50ml of sterile water for injection.

PHARMACOLOGICAL PROPERTIES

D-Fructose 1,6-Diphosphate (FDP) is a glycolytic intermediate which intra-cellularly modulates numerous enzymatic reactions by activating phosphofructokinase, pyruvate kinase and lactate kinase. Its intracellular concentration varies with respect to different cellular species: Human erythrocytes FDP contents makes 6-10 mg/L of a cell.
Biochemical in vitro and in vivo studies indicate that FDP administered in pharmacological dosage, integrates with cellular membrane, facilitates circulating potassium cellular captation, stimulates enriching of both high-energetic intracellular membrane phosphates pool and 2.3 - diphosphoglycerate. In addition, FDP reduces erythrocytes hemolysis undergoing mechanic trauma and inhibits within neutrophils undergoing chemical stimulation, the production of oxygen free radicals.
Pre-clinical studies have demonstrated that FDP favourably influences cardiac metabolism. In an Isolated rabbit heart, it antagonises potassium toxic effects on atrial contractility and accelerates restoration of an efficient cardiac activity after prolonged ischemic cardioplegia. In mouse it reduces biochemical and electrocardiophical manifestations of cytostatic toxicity to heart. It has been demonstrated in rabbit that it facilitates cardiorespiratory reanimation after hypoxic cardiac arrest. In dogs it prevent ATP and creatine phosphate reduction in induced myocardial ischemic limiting necrosis area caused by acute coronary occlusion.
In addition, studies on mice indicate that FDP protects kidneys from functional and histologic damages due to post-ischemic riperfusion.

PHARMACOKINETIC PROPERTIES

FDP, plasmatic concentration measured 5 minutes after infusion of 250 mg/kg in healthy volunteers is 770 mg/l. Eighty minutes after termination of infusion FDP is no observed in detectable quantity. The half-life of plasmatic elimination varies from 10 to 15 minutes.
FDP disappears from plasma due to its extravascular compartment distribution and its hydrolysis in inorganic phosphate and fructose provoked by erythrocytic and plasmatic phosphatase activity.

THERAPEUTIC INDICATIONS

-Treatment of ischemic cardiomyopathies, extensive myocardial infarction in the early stages, cardiac surgery in the extracorporeal circulation time.
-Shock due to cardiac accident, trauma, bleeding, stroke and serious infections.
-During the surgery, FDP is a protective agent against unforeseen complications such as hypotension or decreased oxygen at tissues and maintains the transplanted organs in the body such as the kidney, liver.
-Acute situations in patients treated by transfusion therapies, extracorporeal circulation, parenteral nutrition, after liver surgery, especially in patients burned severely.
-Chronic disease which is ongoing or combines with phosphate deficiency such as acute alcohol poisoning, prolonged malnutrition, respiratory failure with low oxygen levels in the blood, neuroleptic overdose.

DOSAGE AND ADMINISTRATION

FDP should be used for intravenous administration only.
Dosage:
- Recommended daily dose with respect to gravity of condition is within 70-160mg of powder per kg of body weight; or 0.7-1.6ml of drug solution per kg of body weight.
- At acute conditions the medicine is usually administered at the rate of 125-175mg/kg, maximum 250 mg/kg.
-At perioperative myocardial ischemia the medicine should be added to cardioplegic solution just before administration. Prophylactic course of infusions is recommended, 1 vial per day, for 3-5 days prior to surgical intervention.
-In treatment of hypophosphatemia, the administrated quantity must depend on phosphorous deficit avoiding phosphorous excessive load.
-In case of elevated dosage, dividing of daily dosage into two administrations is recommended.
-Children posology is to be established with respect to body weight.

Preparation of injection solution:

-Use the available infusion device for extemporary preparation of the solution.
-Use the available infusion set, administer the drug solution by rapid intravenous infusion with the speed of about 10ml/minute.

Note:

Reconstituted solution is stable for 24 hours at room temperature (under 25°C).
Solution must be used for one application only. Any remaining contents after one application should be discarded.

ADVERSE EFFECTS

-Allergic reactions of an inconsiderable importance to an anaphylactic shock have been rarely observed.
-Infusion with the speed of exceeding 10mL/minute may cause flush, palpitation and extremities formication.
-For any further adverse effect observed during the period of therapy, patients should be reported to a proper doctor in charge.
Inform doctors with side effects when using medicine.

CONTRA INDICATIONS

Known hypersensivity to the drug, hyperphosphatemia, renal insufficiency.

DRUG INTERACTION

There is no evidence of pharmacology interactions.
Compatibility: FDP should not be mixed with other drugs, unsolvable at pH 5.5, as well as with alkaline solutions of potassium salts.

SPECIAL INSTRUCTIONS

Patients with creatinine clearance below 50mL/min the level of phosphates in blood should be monitored all the time.
The drug should be used at young children in case of necessity only, under strict medical supervision.

PREGNANCY AND LACTATION

No adverse effects have been observed in pregnant women when treated with FDP in the last three months of pregnancy.

EFFECTS ON ABILITY TO DRIVE AND TO USE MACHINERIES

Effects of this type are not known.

PRECAUTIONS

Extra-vessel infusion in the subcutaneous tissue during the infusion causes minor pain and local irritations.

OVERDOSE

Excessive dosage symptom have not been reported.

STORAGE CONDITIONS

Dry place, at temperature below 25°C, protect from light.
Do not use the drug if the packaging is damaged.
Keep out of reach of children.

SHELF LIFE

3 years from manufacturing date.
Stability: dissolved FDP is stable for 24 hours at room temperature.
Shelflife period is valid only at proper storage.
Do not used after shelflife expiry.

PACKAGING

Each box of FDP contains: 1 vial of powder + 1 vial of solvent + 1 device for the solution preparation + 1 infusion set.

MANUFACTURER

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