Ulinastatin

Eulip

1. NAME OF THE MEDICINAL PRODUCT

Eulip

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains:

Ulinastatin J.P. ……. 50,000 I.U. / 1,00,000 I.U.

3. PHARMACEUTICAL FORM

Liquid vial for intravenous infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Severe sepsis

Sepsis is defined as a systemic inflammatory response syndrome (SIRS) in the presence of, or as a result of, suspected or proven infection. Severe sepsis is defined as sepsis with one of the following features: cardiovascular organ dysfunction, acute respiratory distress syndrome (ARDS), or dysfunction of two or more organs.

Indian incidence is estimated to be about 750,000 cases per year. The most common causes for sepsis are trauma, burns, abdominal sepsis and pneumonia. Septic shock is the most common cause of mortality in the intensive care unit. Despite aggressive treatment, mortality ranges from 15% in patients with sepsis to 40-60% in patients with septic shock. There is a continuum of clinical manifestations from SIRS to sepsis to severe sepsis to septic shock to Multiple Organ Dysfunction Syndrome (MODS).

4.2 Posology and Method of Administration

Administer 1 to 2 vials of 100,000 I.U. of Ulinastatin by intravenous infusion over 1 hour each time, 1-3 times per day for 3 to 5 days. Reconstitute Ulinastatin in 100 ml of Dextrose 5% or 100 ml of 0.9% normal saline. The dosage may be adjusted according to the age of patients and the severity of symptoms.

4.3 Contraindications

Hypersensitivity to the drug.

4.4 Special Warnings and Special Precautions for Use

- Not to be used for patients who are hypersensitive.
- Not to used in lactating women.
- Ulinastatin should be administered with caution if patient has history of allergy.
- Ulinastatin can NOT replace the traditional therapeutic methods (transfusion, oxygen therapy and antibiotics) for shocks

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

No drug interactions have been reported or noted.

4.6 Fertility, Pregnancy and Lactation

Pregnancy: The safety for pregnant woman is NOT determined yet. Whether or not Ulinastatin should be administered to pregnant woman or potentially pregnant woman may be decided according to the patient's condition.

Nursing mother: Ulinastatin is not used for nursing women. If used, breast feeding should be stopped.

The safe dosage for children is NOT determined yet.

4.7 Effects on Ability to Drive and Use Machines

No information available

4.8 Undesirable Effects

- Rare cases of rash, itching and pain at the site of injection.
- Rare cases of allergy.
- Rare cases of elevation of SGOT and SGPT.
- Rare cases of nausea, vomiting and diarrhea.

4.9 Overdose

No specific antidote is recommended in case of accidental overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Ulinastatin is a protease inhibitor extracted from human urine. Ulinastatin inhibits inflammatory markers: trypsin, pancreatic elastase, polymorphonuclear leukocyte elastase and the endotoxin-stimulated production of TNF alpha and interleukin 1, 8 and 6. It inhibits coagulation and fibrinolysis and promotes microperfusion. Thus, Ulinastatin is an effective agent for immune modulation to prevent organ dysfunction and promote homeostasis.

5.2 Pharmacokinetic Properties

After intravenous injection of 300,000 I.U./10ml into healthy man, its concentration in blood decreases linearly. The half-life of Ulinastatin is about 40 minutes. 6 hours after the administration, 24% of Ulinastatin is discharged in urine.

6. Pharmaceutical particulars

6.1 Shelf life

Two years from date of manufacturing.

6.2 Special precautions for storage

Storage temperature 2°C to 8°C. Protect from light. Any unused portion should be discarded.

7. Marketed BY:

Alkem Labs Limited

Alkem House;

Senapati Bapat Marg,

Lower Parel; Mumbai,

Maharashtra: 400 013.

8. Date of Revision: November 2019