ARTERIUM

L-Lysine aescinat

Comprehensive Prescribing Information

Myanmar FDA Reg. No. 1909 AA 8099

Composition:
Active substance: 1 ml of solution contains 1 mg of L-Lysine Aescinat (equivalent to 100% substance)
Excipients: ethanol 96%, propylene glycol, water for injections.

Pharmaceutical form. Solution for injections.
Pharmacotherapeutic group. Capillary stabilizing agents. Code ATC C05C X.

Clinical particulars
Indications
Post-traumatic, intra- and post-operative edemas of any localization: severe cerebral and spinal edemas including those with intracranial hemorrhage, increased intracranial pressure and dropsy swelling syndrome; excess liquid venous disorders with chronic disorders of cerebral circulation and neurocirculatory asthenia; soft tissue endema involving the locomotor system associated with local blood circulation disorders and pain syndrome; edematous and pain syndromes of the spine, torso, limbs; severe venous circulation disorder in lower limbs against severe thrombophlebitis accompanied by endemous-inflammatory syndrome.
Contraindications
Hypersenitivity to L-Lysine Aescinat and/or other components of the medication;
Severely compromised kidney function;
Severely compromised liver function;
Bleeding;
Pregnancy;
Lactation;
Children under 1 year.

Dosage and administration
The medication should only be injected slowly and intravenously (intra-arterial administration is not allowed!) in a daily dose of 5–10 ml. Intravenous drip injection is recommended. In order to prepare the infusion solution dilute L-Lysine Aescinat in 15–50 ml of 0.9% of sodium chloride solution.
In life-threatening conditions (traumatic brain injury, intra- and post-operative cerebral and spinal edemas with dropsy swelling syndrome, large-scale edemas resulting from major injuries to the soft-tissue and locomotor system) the dose is increased to 20 ml which are to be divided into 2 injections. Maximum daily dose of the medication for adults is 25 ml.
Single dose for children: 1–5 years old — 0.22 mg of L-Lysine Aescinat per 1 kg of bodyweight, 5–10 years old — 0.18 mg/kg, 10 years old and senior — 0.15 mg/kg. The medication is administered twice a day. Duration of the course of treatment — 2 to 8 days depending on condition of the patient and therapy efficiency.

Adverse reactions
In case of individual hypersensitivity to aescinat some patients may develop:
Allergic reactions: skin rash (papular, petechial, erythematous), itching, hyperemia of face skin, fever, urticaria, individual cases — angioedema, anaphylaxis;
Central and peripheral nervous system reactions: headache, dizziness, tremor, paresthesia, individual cases — tottering, balance disorder, temporary loss of consciousness;
Liver and biliary system reactions: increased level of transaminase and bilirubin;
Gastrointestinal tract reactions: nausea, individual cases – emesis, diarrhea, stomachache;
Circulatory system reactions: arterial hypotension, arterial hypertension, tachycardia, pain behind the sternum;
Respiratory organs reactions: individual cases — feeling of lack of air, dyspnea, bronchial obstruction, dry cough;
Local reactions: burning sensation in the vein during injection, phlebitis, pain and endema in injection spot;
Other reactions: general asthenia, rigor, fever, lumbar pain, hyperhidrosis.

Overdosage
Symptoms: fever, tachycardia, menorrhagia, nausea, pyrosis, epigastrium pain.
Treatment: symptomatic therapy

Administration during pregnancy and lactation. Administration of the medication during pregnancy and lactation is counter-indicative (breastfeeding must be terminated during treatment).

Children. The medication is counter-indicative to children under 1 year

Specific administration. Upon prescription of the medication individual patients with hepatocholecystitis may observe temporary increased activity of transaminase and bilirubin (direct fraction) which is not hazardous and does not mean the medication must be changed.

Ability to affect response rate while driving or operating other mechanisms.
At present no information is available, however the possibility of anticipated adverse reactions of the nervous system must be considered while using the medication.

Drug interactions and other types of interactions
Treatment with L-Lysine Aescinat may be combined with other relevant prescribed medications (anti-inflammatory, analgesic, antibacterial).
The medication should not be used simultaneously with aminoglycosides as it can increase their nephrotoxicity.
If long-term therapy with anticoagulants took place before L-Lysine Aescinat prescription or should L-Lysine Aescinat be used simultaneously with anticoagulants corrections of the dose (decrease of the dose) of the latter should be made and prothrombin index must be controlled.
Plasma protein binding with aescin becomes complicated with simultaneous use of cephalosporin antibiotics which may increase the concentration of aescin in blood along with the risk of side effects development of the latter.

Pharmacological properties
Pharmacodynamics. The medication possesses anti-inflammatory, antiedemic and analgesic activity. Aescin decreases activity of lysosomal hydrolases preventing mucopolysaccharide dissolution in capillary walls and connective tissue which surrounds them and in such a way normalizes increased vascular and tissue penetration and has anti-exudative (antiedemic), anti-inflammatory and analgesic properties. The medication increases vascular tone and renders moderate immune-correcting and hypoglycemic effects.

Pharmaceutical properties.
Main physical and chemical properties: clear colourless liquid

Expiration period: 2 years
Storage: Keep away from children. Store in a place protected from light, at the temperature not above 30 °C.
Package: 5 ml of solution in single dose ampoules 5×2
Type of dispensing: on prescription.
Manufacturer: JSC “Halychpharm”
Location: 6/8, Opryshkivska Str., Lviv, 79024, Ukraine
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Model Pharma Co.; Ltd
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