For Veterinary Use Only

L-Anestin®

Local Anesthetic Solution for Injection
Veterinary Local Anesthetic

COMPOSITION:

L-Anestin Solution for Injection is a clear, colorless, viscous solution containing 20 mg lidocaine HCl and 0.010 mg adrenalin (epinephrine) per ml.

PHARMACOLOGICAL PROPERTIES:

One of the L-Anestin Solution for Injection active substances lidocaine, according to the specific receptor theory, inhibits Na+ passing by being bonded to specific receptors in Na+ channels. It is easily penetrated through tissue-barriers and nerve sheath because of its non-ionized form lipophilic characteristics and it passes the membrane, but does not pass ionized form tissue barrier. Non-ionized form passing through the membrane is converted to be ionized by axoplasm pH. This ionized form is reacted to specific receptors on the inner surface of Na+ channel, bonds to them, and blocks the transmission. During local anesthesia uptake from administration area is dependent on perfusion degree; peak serum level is reached within 15-30 minutes. Adrenalin, other active substance, is a vasoconstrictor agent declining systemic absorption of local anesthetic by decreasing perfusion at the injection area. This is valid especially for procaine, lidocaine, and mepivacaine like short and average effective agents. By this mechanism;

a) Neuronal uptake of drug gets increased and systemic toxic effect gets declined because blood level is decreased for an average of 33%.

b) Decline in systemic absorption, and increase in uptake by nerve make anesthetic effect increased 50%, and it prolongs time course of drug action. Thus anesthesia for a period of one hour to a few hour depending on concentration and its dosage. Lidocaine is a few times better than procaine in terms of absorption and time course of action, and 78% of it becomes involved in circulation. Protein binding rate is 64%, pKa 7.9, and lipid/water partition factor is 2.9. Considerable part of it is hydrolyzed in liver. Around 10-20% of it is catabolized in kidneys. Adrenalin is not absorbed through proper skin. It is absorbed very slowly and its clear systemic effect starts lately because it causes local vein stenosis.

AREA OF USE / INDICATIONS:

L-Anestin Solution for Injection is used for all forms of local anesthesia; lower and upper epidural anesthesia, infiltration (layer) anesthesia and area blockage; removing neurotic sense (nerve blockage); spinal (medullar) anesthesia; and paravertebral anesthesia in non-edible animals (horse, cat, and dog). It is indicated in difficult birth, vaginal and rectal prolapsus, laparotomia, castration, tail and ear amputations, breast tumour resection, and simple surgery procedures, and in all kind of application requiring local anesthesia.

USAGE AND DOSAGE:

It is administered into subcutaneous tissues, epidural space, and around nerves as follows:

*** Infiltration anesthesia**

To an area of 1 ml (20 mg) / cm^2 as per the size of area needed for subcutaneous infiltration anesthesia.

*** Nerve Blockage**

Horse 2 (40 mg) - 15 (300 mg) ml (it could be used up to 30 ml when needed.)

*** Epidural Anethesia**

Horse	5 – 20 ml
Cat-Dog	1 - 10ml (20 mg/ 4.5 kg)

*** Castration**

Horse	10 ml
Dog	1 – 2 ml
Cat	0.5 – 1 ml

*** Paravertebral Anesthesia**

Horse	10 – 20 ml

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR INTENDED SPECIES:

L-Anestin dose is needed to be adjusted in accordance with local anesthesia technique, needed anesthesia depth and time, vascularization of the administration area, and individual reaction of the animal. Avoid intravenous administration, and ensure cannula not being in vein by aspirating the syringe before injection.

Be aware when using in acidosis, diabetes mellitus, congestive heart failure, liver failure, severe respiratory diseases, hypovolemia, and distinct hypoxia or shock situations. Remember it may cause ischemia at body areas with insufficient blood stream because of its vasoconstrictor agent ingredient. In equidae it is used for only local and regional anesthesia.

Injection should be performed in sterile conditions; attention is needed to be paid to not form contamination. Local antibiotic administration is recommended for operation area. Maximum useful doses for infiltration anesthesia in horse and dogs are 300 ml, and 30 ml, respectively.

UNDESIRED/SIDE EFFECTS

Systemic effects including tachycardia, cardiac conductivity defects, low blood pressure, and allergic reactions may be observed. It may suppress myocardium because it passes easily through placenta in pregnant. Sensitive animals may develop hypersensitivity.

DRUG INTERACTIONS:

Long-term hypertension may be observed as a result of L-Anestin Solution for Injection administration in patients treated with mono amine oxidase (MAO) inhibitors or tricyclic antidepressants. Be aware when using lidocaine by combining it with procainamide, metoprolol or propanolol like p-adrenergic blocker agents because it decelerates lidocaine elimination and metabolism, and avoid using in animals with cardiac disease. It is not compatible with amphotericin, methohexital sodium, sulfadiazine, and cefazolin sodium. Epinephrine-like substances given at the same time with anesthesia prolongs anesthesia period. Morphine-like painkillers accelerate lidocaine metabolism. Avoid using pentobarbital with lidocaine in dogs. It should not be used especially together with drugs highly bonding to proteins before the effect of anesthetic goes down.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

In case of overdose it may cause nausea, vomiting, excitation, low blood pressure, and contractions considerable as clonic convulsion. In case of exceeding the recommended dosage diazepam or short efficient barbiturates should be administered in order to cure possible convulsions. In severe situations oxygen support should be provided.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): Do not use in meat type animals.

CONTRAINDICATIONS:

Use during pregnancy: Avoid using in late periods of pregnancy especially if it would not be used in order to terminate pregnancy. It should be used carefully and controlled if necessary. It is contraindicated in animals with ventricular dysrythmia and myocardial failure. Its administration is contraindicated to animals with shock and cardiac block, neurological diseases, spinal damages, septicaemia, and hypertension; and in case of sepsis existence on the administration area. Local anesthetics should not be administered in phlegmon, necrosis, fragmented wound and tissues formed by induration. Intravenous administration is inappropriate. 2 maximum doses should not be used within 24 hours.

GENERAL WARNINGS:

Subject to veterinary surgeon's prescription. Keep out of reach of children. Consult your veterinary surgeon in case an unexpected effect is observed.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS:

Avoid contact with skin and eyes. Wash with plenty of water if the product contacts with skin. Wash your hands after administrating medicine. Measures should be taken against possible self-injections.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:

Empty packages should be tossed out. It should not be used for different purposes.

STORAGE CONDITIONS AND SHELF LIFE:

Store in a dry and cool place, keep away from light.
Shelf life is 3 years as of the production date.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE:

Offered for sale in cardboard boxes as 20 ml and 50 ml amber vials and 10 ml ampoules (in boxes containing 5 ampoules).

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 17.12.2004

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS AUTHORIZATION DATE AND NO: 26.03.1997-8/804

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-ISTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

Alke Sağlik Ürünleri San. ve Tic. A.Ş

Merkez Organize Sanayi Bölgesi 2. Kısım 10. Cadde No:7 Tokat