Only for Veterinary Use

Actipen LA

Suspension for Injection

Veterinary Systemic Antibacterial

COMPOSITION

Actipen-LA Suspension for Injection is a white color (when agitated), ready-to-use and sterile suspension for injection and it contains 100.000 IU procaine penicillin G, 100.000 IU benzathine penicillin and 200 mg dihydrostreptomycin sulphate (in sulphate salt form) per ml. solution.

PHARMACOLOGICAL PROPERTIES

Actipen LA Solution for Injection is broad-spectrum formulation with long-term effect which is effective against many Gram-positive and Gram-negative bacteria susceptible to penicillin and dihydrostreptomycin. Procaine penicillin G and benzathine included in the combination caused death of susceptible bacteria by inhibiting cell wall synthesis of bacteria, particularly in reproduction phase. This enables streptomycin to penetrate bacteria at higher concentrations. Thus, penetrating into bacteria at higher concentration, dihydrostreptomycin provides its effects by inhibiting protein synthesis. This combined and synergistic effect is characterized with bactericide effect even at very low doses. As penicillin is effective against gram-positive bacteria and dihydrostreptomycin is effective against gram-negative bacteria, spectrum is expanded by synergistic effect.

Synergistic effect arising from penicillin-dihydrostreptomycin combination has a broad-spectrum covering both gram-positive and gram-negative bacteria. It was shown that the combination is in-vitro effective against following bacteria. Corynebacterium pyogenes, Klebsiella pneumoniae, Listeria sp., Pasteurella haemolytica, P. multocida, Staphylococcus sp., Streptococcus sp., peptostreptococcus sp., Erysipelothrix insidiosa, Clostridium sp., Escherichia coli, Proteus sp., Moraxella sp., Actinobacillus lignieresi, Haemophilus sp., and Salmonella sp.

Procaine penicillin G contained in the composition of Actipen LA is absorbed in injection site within 30 minutes and concentrations above MIC required for susceptible bacteria are reached. Due to reservoir effect, benzathine penicillin is gradually absorbed from injection site resulting with at least 48 hours of efficiency. It is in partially free form in blood and partially protein-bound (penicillin 80-90 % and dihydrostreptomycin 30 percent). It penetrates to kidney, liver, lung, skin and soft tissue, mucosa, serosa and connective tissue. Without undergoing metabolic change, it is in large part, 80-90 percent, excreted from kidneys and it is also excreted from biliary system, milk and perspiratio in low amounts.

AREA OF USE/INDICATIONS

Actipen LA Suspension for Injection is used in the cow, horse, sheep and dogs for treating systemic and local infections, respiratory, gastrointestinal and urinary system infections caused by susceptible bacteria as well as secondary bacterial infections.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Unless otherwise advised by the veterinary surgeon:

Practical dose: 1 ml / 20 kg live body weight dose is administered via intramuscular route.

Horse, Cattle	(400 kg live body weight)	20 ml
Calf, Heifer	(200 kg live body weight)	10 ml
Kid, Colt	(100 kg live body weight)	5 ml
Sheep	(40 kg live body weight)	2 ml
Dog	(10 kg live body weight)	0.5 ml

In general, single dose will be sufficient, but second dose can be administered in 3-day intervals when required.

Before use, agitate bottle well and thus, suspension is homogenized.

Intravenous administration is contraindicated.

Procedures of asepsis and antisepsis should be observed during use.

Repeated administrations to the same site should be avoided particularly in horses.

ADVERSE / SIDE EFFECTS

Urticaria, dermatologic lesions, nausea, vomiting, difficulty in breathing (dyspnoea), lung and larynx oedema, paralysis of vasomotor center and coma, allergic and anaphylactic side effects and death can be observed in sensitive animals. High plasma streptomycin concentrations occurred in dose-dependent manner particularly in animals with renal dysfunction may cause neurotoxic, nephrotoxic and autotoxic effects. Dose should be accordingly adjusted in renal insufficiencies.

DRUG INTERACTIONS

It is not physically and chemically compatible with calcium, sodium, potassium and dextrose solutions, acid and alkaline, chlorothiazide, phenobarbitone, phenytoin sodium, Vitamin C and B group vitamins and it has antagonistic interaction with tetracyclines, ampicillin, cloxacillin, methicillin, carbenicillin, sulphadiazine and nitrofurantoin. It should not be used with the drugs known to be nephrotoxic, autotoxic and neurotoxic and/or known to increase toxic effects of dihydrostreptomycin (other aminoglycosides, furosemide, sulphonamides, tetracyclines, anesthetics, cephalosporins etc) due to possible toxic effects of dihydrostreptomycin. Moreover, it should be noted that penicillin and streptomycin concentrations, particularly in high doses, may cause mortality as they may increase neuromuscular blockade in animals administered general anesthetics and/or muscle relaxants.

WARNINGS FOR THE DRUG RESIDUES IN THE NUTRIENTS

Withholding Period (WHP): *The cattle and the sheep must not be sent to slaughter throughout treatment and for 60 days following administration. Milk of animal obtained throughout treatment and within 15 days (30 milking) following last administration should not be offered to consumption by human. Since the drug Withholding Period is long for the milk, it is not recommended to administer to the cow and sheep fed for obtaining milk to provide to human consumption.*

CONTRAINDICATIONS

It should not be used in animals with highly sensitive to penicillin, cephalosporin and dihydrostreptomycin and also animals with advanced renal dysfunction. Intravenous administration is contraindicated.

During pregnancy: Penicillin is an antibiotic compound which can be safely used during pregnancy. Side effects of streptomycin and dihydrostreptomycin on sperm quality, reproductive efficiency and intra-uterine growth of fetus were not observed. It was demonstrated that both antibiotics had no teratogenic effect on guinea, rats and rabbits.

WARNING FOR NON-TARGETED SPECIES

As the case in other penicillin compounds, it should not be used in small herbivore animals such as hamster, rabbit and rat as well as totipalmate animals such as goose and duck. Cats are relatively more sensitive to streptomycine. Therefore, streptomycin containing preparations should not be administered to cats.

GENERAL WARNINGS

Please refer to the veterinary surgeon before use and in case of an unexpected effect. Keep out of reach of the children.

OVERDOSE AND PRECAUTIONS TO BE TAKEN

Deafness which may occur when the drug is administered at doses and periods exceeding the recommendations may not be treated if it became irreversible. If sensitivity related side effects occur, drug administration should be ceased and treatment should be started with cardiac and respiratory analeptics, antihistamines, corticosteroids and adrenalin according to resultant clinic picture.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR

Please avoid contact with the drug and wash your hands after use.

Individuals known to be sensitive to penicillin and cephalosporin should no means contact the drug. Following exposure of sensitive individuals with the drug due to contact with oral cavity, skin or via inhalation, emergency medical intervention may be required for swelling in face, eyes or lips and difficulty in breathing. In this case, doctor should be contacted with the drug and prospectus in hand.

STORAGE CONDITIONS AND SHELF LIFE

Shelf life is 2 years from the date of production. Protect from the light. Protect from freezing. Store at temperatures between 2 and 15 ℃.

It maintains efficiency for 28 days from the first use of the drug if it is stored in accordance with the instruction included in interior of the package. Opened vials should be stored in refrigerator (+2-8ºC).

COMMERCIAL SUPPLY INDICATING COMPOSITION AND QUANTITY OF PACKAGING

Actipen LA Suspension for Injection is commercially available in 20, 50 and 100 ml colorless glass vials packed into cardboard boxes as well as 250 ml colorless glass vials packed into plastic box.

SALE PLACE AND CONDITIONS

It can be sold in the veterinary offices and the pharmacies with the prescription written by veterinary surgeon (VP).

PACKAGE INSERT VALIDATION DATE: 31.10.2011

DATE AND NUMBER OF LICENSE AWARDED BY THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS: 18.10.2011- 24/094

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