For Veterinary Use Only

TRIOCOM®

Suspension for Injection

Veterinary Systemic Antibacterial

COMPOSITION

TRIOCOM Suspension for Injection white, greasy, sterile suspension containing 100 mg ampicilline 250 000 IU colistin sulphate and 0.25 mg dexamethasone per ml.

PHARMACOLOGICAL PROPERTIES

It is a semi-synthetic broad spectrum penicillin containing ampicilline beta-lactam ring. Its bactericide activity is shown inhibating bacterial cell wall biosynthesis.

Sensitive bacteria: Most of gram positive bacteria including beta hemolitic Streptococcus (Strep.agalactiae, S.canis, S.zooepidemicus, S.dysagalacıiae, S.suis. S.ubcris, Bacillus anthracis, Actinomyces sp., most of Corynebacter sp., Erysipelohtrix rhusiopathiae, most of Listeria monocytogenes), some anaerobes (Clostridium sp., most of Fusobactcrium sp., some Bacteroides sp.). some gram negative aerobes (Haemophilus somnus). Borrelia sp., Leptospira sp., Actinobacillus sp., Haemophilus sp., Leptospira sp., Moraxella sp., Pasteurella sp., Proteus sp., Taylorella equigeniitalis, Serpulina sp., Campylobacter sp., Enterococci, Rhodococcus equi.

Resistancy development in enterobacteriaceae is common. Bacteroides fragilis, Bordetella bronchiseptica, Citrobacter sp., Entcrobacter sp., Klebsiella sp., other Proteus sp., Pseudomonas aeroginosa, Serratia sp., Yersinia enterocolitica are ampicilline resistant. It is not efficient in bacteria releasing beta lactamase.

When administered intramuscularly at 6 mg/ kg dose in cattle, it reaches to peak plasma concentration (8.5 µg/ml) within 1 hour. It disperses into all tissues excluding cranial cerebrospinal fluid. Its level in blood becomes 0.3 µg/ml after 6 hours, and it becomes non-detectable after 24 hours. Its bonding rate to serum proteins is low (20%). Elimination half-life is 1.35 hours. It is eliminated by unchanged excretion of the drug and in the form of inactive penicilloic acid (10-25%) through kidneys.

Colistin is included in polimyxin group antibiotics. Its bactericide and bacteriostatic effect is based on failure of sensitive bacterial cell membrane permeability It fails cell structure by being penetrated through reacting membrane phospolipids. Consequently cell content, especially purine and pirimidins apart from cell protoplasm. Real lysis is formed in sensitive bacteria. Antibacterial spectrum of colistin is limited with Gram (-) bacteria. Aerobacter aerogenes, E. coli, Salmonella spp., Shigella spp, Pseudomonas aeroginosa, Vibrio spp, and paracolon bacteria are sensitive to colistin sulfate. Large part of Proteus spp and Serratia spp is resistant.

It is rapidly and well absorbed parenterally, and reaches peak blood concentration within 1 hour. Elimination half-life is 5-6 hours.

Dexamethazone is a glucocorticoid with higher antiinflammatory activity, which is established by adding a methyle group to 16 position of a fluoro-prednisolone molecule. Rapidly absorbed through administration area. It disperses well into tissues, intertissue fluid, and cranial cerebrospinal fluid. It is metabolized in liver. Essentially it is excreted through urination, and through ballast and gaita for small amounts.

INDICATIONS

In cattle, caused by sensitive bacteria;

Respiratory infections (such as secondary infections accompanying bronchitis, bronchopneumonia, pneumonia, Pasteurella pneumonia, enzootic pneumonia, and viral pneumonia),

Acute mastitis in milch cows

It is used in septicemic infections of baby and young animals.

USAGE AND DOSAGE

Unless recommended otherwise by veterinary surgeon, 1 ml Triocom Suspension for Injection is administered intramuscularly for 10 kg live weight. Pharmacological dose for ampicillin is 10 mg/kg live weight, for colistin 25000 IU /kg live weight, and for dexamethasone 0.025 mg/kg live weight.

Practice dose;

Live weight (kg)	Drug amount to be administered	Administartion Type	Administartion Term
50 kg	5 ml	Intramuscular	3 - 5 days
100 kg	10 ml	Intramuscular	3 - 5 days
500 kg	50 ml	Intramuscular	3 - 5 days

In case it is administered more than 20 ml in cattle the dose should be separated into two volumes, and should be injected to two different area. Shake the bottle before use.

UNDESIRED/SIDE EFFECTS

Subsequent to the administration animals should be observed in terms of immunodepressant corticosteroid effects. Parenteral colistin may cause nephrotoxic and neurotoxic effects in especially overdose and long-term use cases. Polymyxin may cause balance disorder, descreased sensation level in head, arm and leg skin, and weakness in muscles in parenteral administration. Tissu accumulations is increased in kidney failure and administration at higher doses.

Most significant penicilline side effects are acute anaphylaxis and collapse. Besides hypersensitivity reactions (e.g. urticary, fever, angioneurotic, etc.) may be observed less strongly but more frequently. In case of anaphylaxis formation antihictaminic or glucocorticoid administration is needed.

DRUG INTERACTIONS

Renal toxicity risk gets higher when used together with polymyxins and cephalosporin. When polypeptide antibiotics used together with nondepolarizing neuromuscular blocking agents they may cause an increment in neuromuscular effects.

It decelerates Prohenecid. ampicilline tubular secretion, increases elimination half-life. Do not use together with bacteriostatic antibiotics including amoxicillin tetracyclines, sulfonamides. Diuretics may decrease antibiotic concentration because they accelerate amoxycillin excretion. Allopurinal-like uric acid synthesis inhibitors increase skin reaction formation risk.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

5 fold the recommended dose does not cause any intolerance sign in cattle.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP): Meat type cattle should not be sent for slaughtering during treatment and before 21 days after the last drug administration. Any milk acquired during treatment or within 10 milkings (5 days) after the final drug administration should not be offered for human consumption.

CONTRAINDICATIONS

Do not use in serious renal failures accompanied by anuria and oliguria. Avoid administrating in animals with known hypersensitivity to penicillin.

Use during pregnancy: It is not safe to use during pregnancy.

GENERAL WARNINGS

Consult your veterinary surgeon before using and in case an unexpected effect is observed. Keep out of reach of children.

Shake the bottle before use.

Keep away from food products.

Do not purchase and use the products with damaged packages.

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

It is possible individuals sensitive to penicillin, cephalosporin, etc. to be also sensitive to ampicilline. As a result of intake through skin contact, inhalation, injeciton, or any other way allergic reaction may be observed in sensitive individuals.

- If you know your sensitivity or if you are not allowed to work with such preparations, do not contact the product by your hands.
- Contact the product after taking all precautions.
- If symptoms are observed to be developed seek for medical assistance immediately. Medical precautions should be taken in case of face, lip, or eye puffiness or difficulty in breathing.
- Wash your hands after using it.

STORAGE CONDITIONS AND SHELF LIFE

Shelf life is 2 years as of the production date. Keep under 25º C away from sunlight, and do not freeze.

WARNINGS FOR NON-TARGET SPECIES

Amoxicilline is not used in rabbit and hamsters similar to other penicilline derivatives. Besides do not use in snakes and poultry with totipalmate feet (e.g. goose).

COMMERCIAL PRESENTATION FORM

Offered for sale as 20, 50, and 100 ml colourless glass vials in cardboard box packages, and as 250 ml in plastic cans.

PLACE AND CONDITIONS OF SALE

Sold with Veterinary Surgeon’s prescription in pharmacies and veterinary surgeries. VSP

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