

For Animal LUse Only.

SHOTAPEN® L.A.

Injectable Suspension

Veterinary – Systemic Antibacterial

Composition:

SHOTAPEN L.A. is a white, sterile suspension for injection containing:

- 73.58 mg benzathine penicillin G,
- 56.80 mg procaine penicillin G,
- 164 mg dihydrostreptomycin sulfate per 1 mL.

It also contains preservatives sodium methylparaben and sodium propylparaben, and an antioxidant sodium formaldehyde sulfoxylate.

Pharmacological Properties

Pharmacodynamics:

Penicillin G is a time-dependent bactericidal antibiotic that works by blocking bacterial cell wall biosynthesis during the bacterial growth phase. Its spectrum is mainly limited to Gram-positive bacteria and Pasteurella.

Dihydrostreptomycin is a bactericidal antibiotic that works by disrupting bacterial protein biosynthesis and the permeability of the bacterial cell membrane. Its spectrum targets Gram-negative bacteria.

The combination of these two antibiotics results in a synergistic effect in vitro; penicillin enhances the penetration of dihydrostreptomycin into the bacteria. The combination has complementary effects on Gram-negative bacteria (e.g., Pasteurella, Histophilus, Actinobacillus), Gram-positive bacteria (e.g., Staphylococci, Streptococci, Corynebacteria, anaerobic bacilli, Erysipelothrix), and spirochetes.

Sensitivity:

MIC50 and MIC90 values for the target bacteria are summarized in the table below, for both the penicillin-streptomycin combination and penicillin alone.

Bacteria	Species	Tested drugs	MIC 50 (µg/mL)	MIC 90 (µg/mL)
<i>Corynebacterium</i> spp	Cattle	Penicillin/Streptomycin (1:2)	0.25	0.25
<i>Staphylococcus</i> spp	Cattle	Penicillin/Streptomycin (1:2)	0.06	1
	Dog	Penicillin	0.12	8
<i>Streptococcus</i> spp	Cattle	Penicillin/Streptomycin (1:2)	0.25	0.5
	Dog	Penicillin	0.008	0.015
<i>Histophilus somni</i>	Cattle	Penicillin/Streptomycin (1:2)	≤0.004	0.015
<i>Mannheimia haemolytica</i>	Cattle	Penicillin/Streptomycin (1:2)	0.12	0.25

Bacteria	Species	Tested drugs	MIC 50 (µg/mL)	MIC 90 (µg/mL)
<i>Pasteurella multocida</i>	Cattle	Penicillin/Streptomycin (1:2)	0.12	0.25
	Dog	Penicillin	0.12	0.5

Pharmacokinetic Properties

After parenteral administration, the benzathine salt form of penicillin G is released more slowly than the procaine salt form, ensuring effective blood concentrations for up to 72 hours. It is rapidly and primarily excreted unchanged in the urine (80%).

A large portion of dihydrostreptomycin administered parenterally is excreted unchanged via the kidneys. However, some remains in the renal cortex, leading to prolonged excretion.

Indications / Field of Use

SHOTAPEN L.A. is used in cattle and dogs (both young and adult) for infections of the respiratory, digestive, and urogenital systems, septicemias, and secondary infections caused by sensitive bacteria occurring alongside viral infections. It is also used in other soft tissue infections. Specific uses include:

- Infectious pneumonia,
 - Actinomycosis,
 - Leptospirosis,
 - Umbilical infections,
 - Mastitis and metritis (as adjunctive treatment).
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Dosage and Administration

SHOTAPEN L.A. is administered intramuscularly in cattle, intramuscularly or subcutaneously in dogs. It should not be administered intravenously. Shake the bottle well before use to homogenize the suspension.

Unless otherwise recommended by a veterinarian, the following dosages are used:

- **In cattle:** Administer 10 ml per 100 kg body weight (equivalent to 13.1 mg of benzylpenicillin and 16.4 mg of dihydrostreptomycin per kg body weight) either once or twice with a 72-hour interval between doses.
- **In dogs:** Administer 1–2 ml per 25 kg body weight (equivalent to 5.3–10.6 mg of benzylpenicillin and 6.7–13.1 mg of dihydrostreptomycin per kg body weight) either once or twice with a 72-hour interval between doses.

Accurate body weight measurement is essential for proper dosing. Aseptic technique should be followed, and repeated injections into the same site should be avoided.

Special Clinical Information and Warnings for Target Species

Improper use of this product may increase the prevalence of bacteria resistant to penicillin or dihydrostreptomycin.

In animals with kidney failure or dehydration, dose adjustments should be made with caution.

Use During Pregnancy and Lactation

Studies in laboratory animals did not show any teratogenic effects for the active ingredients. However, there are no studies conducted in target species, so the use of this veterinary product should be based on the veterinarian's benefit-risk assessment.

Adverse Effects

- **Non-dose-dependent reactions:** Hypersensitivity reactions to procaine penicillin may occur.
- **Allergic reactions:** Skin reactions, anaphylactic shock may occur.
- **Injection site reactions:** Local skin reactions may occur following injection.

If any serious side effects or unexpected effects occur, consult a veterinarian.

Drug Interactions

SHOTAPEN L.A. is incompatible with:

- Tetracycline, oxytetracycline, aminophylline, amikacin sulfate, cefalotin sodium, chlorpromazine, amphotericin B, vitamin C, B vitamins, novobiocin, dicloxacillin (due to antagonism), dimenhydrinate, acids, alkalis, metal ions, oxidants, reducers, and glycerin.

When used with antipyretic and anti-rheumatic drugs (especially phenylbutazone and salicylates), the excretion of penicillin through the kidneys may be delayed. Penicillin should not be combined with bacteriostatic antibiotics (e.g., tetracyclines, sulfonamides, phenicols, macrolides) as this may suppress its bactericidal activity.

Dihydrostreptomycin should not be combined with other nephrotoxic, ototoxic, or neurotoxic drugs (e.g., other aminoglycosides, furosemide, sulfonamides, tetracyclines, anesthetics, cephalosporins) due to the increased risk of toxicity.

Overdose Symptoms, Measures, and Antidotes

In case of overdose, dihydrostreptomycin can cause neuromuscular blockade, leading to flaccid paralysis and cardiac-respiratory depression. Intravenous calcium can help mitigate this.

Food Residue Warnings

Withdrawal Period (WDP):

- **For meat:** Cattle treated with this product must not be slaughtered for consumption for at least 77 days after the last administration.
 - **For milk:** Milk should not be consumed within 8 days (16 milkings) after the last administration.
Due to the long milk residue clearance time, this product is not recommended for use in cows that will be used for milk production.
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Contraindications

Do not administer to animals known to be allergic to penicillins or local anesthetics.

General Warnings

Read the prospectus before use. Consult a veterinarian before use and if unexpected effects occur. Use with caution in animals sensitive to penicillin.

Keep out of reach of children and store in the original packaging.

Precautions for the User and Warnings for Healthcare Providers

This product should be used with proper precautions. Wash hands after use.

Penicillin and cephalosporins can cause allergic reactions after injection, inhalation, ingestion, or skin contact. Sensitivity to penicillin may cause cross-reactivity with cephalosporins. Such allergic reactions may be severe but are rare. Similarly, local anesthetics can also cause allergic reactions.

If you are aware of sensitivity to these substances, do not use this product. If contact with the eyes occurs, rinse immediately with plenty of water. If skin redness, swelling of the face, lips, or eyes, or difficulty breathing occurs, seek immediate medical attention.

Storage Conditions and Shelf Life

Store between 2–8°C, away from light. The shelf life is 18 months.

Once opened, it should be used within 28 days if stored at 2–8°C. Do not store above 25°C after opening. The stopper can be punctured at least 28 times.

Do not freeze and protect from sunlight.

Disposal and Warnings for Non-target Species

This product should not be used in small herbivorous animals (e.g., hamsters, rabbits, guinea pigs), waterfowl (e.g., ducks, geese), or cats (as they are particularly sensitive to dihydrostreptomycin). Any unused veterinary medicinal product or waste material must be disposed of in accordance with national regulations.

Commercial Presentation

SHOTAPEN L.A. is available in 50 ml, 100 ml, and 250 ml glass vials with rubber stoppers and aluminum caps, or in 100 ml and 250 ml PET bottles, both in cardboard packaging with a plastic protector.

Place and Conditions of Sale

Available by veterinary prescription at veterinary clinics and pharmacies (VHR).

Prospectus Approval Date

T.C. Ministry of Agriculture and Forestry Marketing Authorization Date and No:
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