Leaflet

For Veterinary Use Only

SPİRAVİL

Solution for Injection

Veterinary Systemic Antibacterial

COMPOSITION

It is a clear, pale yellow, sterile solution containing 600,000 IU spiramycin per ml.

PHARMACOLOGICAL PROPERTIES

Spiramycin, contained in Spiravl Solution for Injection, is an antibiotic belonging to the macrolide group, obtained from Streptomyces ambofaciens cultures. It binds to the 50S ribosomal subunit in bacteria, inhibiting the elongation of the peptide chain and thereby disrupting protein synthesis.

Spiramycin is effective against Gram-positive and Gram-negative bacteria, as well as *Mycoplasma* and *Chlamydia*. Sensitive bacteria include *Staphylococcus* species (including penicillinase-producing strains), *Streptococcus* species, *Corynebacterium pyogenes, Clostridium perfringens, Mycoplasma species, Pasteurella haemolytica, Pasteurella multocida, Haemophilus somnus, Fusobacterium necrophorum, Bacteroides species, Enterococcus species, Neisseria intracellularis, Listeria monocytogenes, Corynebacterium diphtheriae, Leptospira ictero-hemorrhagiae, Toxoplasma, Brucella*, and *Rickettsia* species.

After intramuscular administration in calves, peak plasma concentration is reached within 1 hour, at a level of 2.32 µg/ml. The drug distributes throughout the body tissues, particularly found in high concentrations in the milk ducts, lungs, pleura, and bronchial fluid. The drug is primarily excreted unchanged via bile.

AREA OF USE/INDICATIONS

It is used in cattle for the treatment of mastitis caused by spiramycin-sensitive microorganisms (including *Streptococcus spp*., *Staphylococcus spp*., and *Mycoplasma spp*.), foot rot, respiratory infections (enzootic pneumonia caused by *Pasteurella spp*. and *Mycoplasma spp*.), arthritis, metritis, enteritis, omphalophlebitis, and omphalitis.

USAGE AND DOSAGE

Pharmacological dose for adult cattle: 30,000 IU spiramycin / kg body weight is administered deep intramuscularly once.

Practical dose: 1 ml / 20 kg body weight.

Pharmacological dose for calves: 75,000 IU spiramycin / kg body weight is administered deep intramuscularly once.

Practical dose: 2.5 ml / 20 kg body weight.

If necessary, the dose may be repeated after 24 hours.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

No more than 15 ml of the drug should be administered at a single injection site; if a larger amount is needed, the total dose should be divided and injected into separate sites.

ADVERSE EFFECTS

No side effects have been observed when used at the recommended doses.

DRUG INTERACTIONS

Spiravil should not be mixed with other parenteral solutions. It should not be used concurrently with phenicols and lincosamides due to competitive receptor binding.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Spiramycin has a wide safety margin; no clinical signs have been observed even when used at 10-15 times the recommended doses. At very high doses, neurological symptoms, salivation, and tremors may be seen.

WITHDRAWAL PERIODS

Meat: 21 days
Milk: 7 days (14 milkings)

CONTRAINDICATIONS

No known contraindications.
Use during pregnancy: Studies conducted on rats have shown no adverse effects of spiramycin on pregnancy. Studies on target animal species are not available.

GENERAL WARNINGS

Consult a veterinarian before use and if any unexpected effects occur. Keep out of reach of children.

STORAGE CONDITIONS AND SHELF LIFE

It should be stored at room temperature (15–25ºC), protected from light. Shelf life is 2 years.

COMMERCIAL PRESENTATION FORM

50 ml, 100 ml and 250 ml colorless glass flacons in cardboard boxes.

PLACE AND CONDITIONS OF SALE

Sold with a veterinarian's prescription in pharmacies, veterinarian offices, polyclinics and animal hospitals. (VSP)

APPROVAL DATE OF LEAFLET: 21.10.2008

MARKETING AUTHORIZATION DATE AND NO: 26.09.2008-020/0055

MARKETING AUTHORIZATION HOLDER
VİLSAN Veteriner İlaçları Tic. ve San. A.Ş.
Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No:765A Akyurt/Ankara-Türkiye

MANUFACTURER COMPANY
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Made in Turkiye

Box

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Practical dose for calves: 2.5 ml / 20 kg body weight is administered deep intramuscularly once.
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Label

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