

LINCOCIN®

NDC 0009-0595-05, NDC 0009-0596-02, NDC 0009-0475-01, NDC 0009-0570-01, NDC 0009-0617-01

brand of lincomycin hydrochloride products

For Use in Animals Only

For intramuscular, intravenous, and oral use in dogs and cats.

DESCRIPTION

LINCOCIN products contain lincomycin hydrochloride, an antibiotic produced by *Streptomyces lincolnensis* var. *lincolnensis*, which is chemically distinct from all other clinically available antibiotics and is isolated as a white crystalline solid. It is stable in the dry state and in aqueous solution for at least 24 months. Lincomycin hydrochloride is readily soluble in water at room temperature in concentrations up to 500 mg/mL. Physical stability of aqueous solutions can be maintained at drug concentrations up to 345 mg/mL at temperatures as low as 4° C. The solubility in 95 percent ethanol is 80 mg/mL.

LINCOCIN products have been shown to be effective against most of the common gram-positive pathogens. Depending on the sensitivity of the organism and concentration of the antibiotic, it may be either bactericidal or bacteriostatic. It has not shown cross resistance with other available antibiotics. Microorganisms have not developed resistance to LINCOCIN rapidly when tested by *in vitro* or *in vivo* methods.

ACTIONS

Animal Toxicology—The acute LD₅₀ intraperitoneally in mice is 1000 mg/kg and orally in rats is 15,645 mg/kg. LINCOCIN was well tolerated orally in rats and dogs at doses up to 300 mg/kg/day for periods up to one year. Parenteral dosages of up to 60 mg/kg/day for 30 days subcutaneously in the rat and intramuscularly in the dog produced no significant systemic effects or pathological findings at necropsy.

LINCOCIN at a daily dose level of 75 mg/kg subcutaneously was injected into mature male and female rats during a prebreeding period of 60 days and throughout two mating cycles (84 days). No evidence was obtained that LINCOCIN exerted any effects on breeding performance and no drug-induced anomalies were discovered in the young. Similarly no evidence was obtained that LINCOCIN, when given in sustained parenteral dosage of 50 mg/kg daily to pregnant bitches, produced a teratogenic effect on the canine embryo.

The subcutaneous LD₅₀ value in the newborn rat was determined to be 783 mg/kg. Newborn rats and canine pups have tolerated multiple doses of 30-90 mg/kg/day of the drug without evidence of ill effects.

Biological Studies—*In vitro* studies indicate that the spectrum of activity includes *Staphylococcus aureus*, *Staphylococcus albus*, *β-hemolytic Streptococcus*, *Streptococcus viridans*, *Clostridium tetani*, *Erysipelothrix insidiosus*, *Mycoplasma* spp., and *Clostridium perfringens*. The drug is not active against gram-negative organisms or yeasts.

In vivo experimental animal studies demonstrated the effectiveness of LINCOCIN in protecting animals infected with *Streptococcus viridans*, *β-hemolytic Streptococcus*, *Staphylococcus aureus*, *Erysipelothrix insidiosus*, *Mycoplasma* spp., and *Leptospira pomona*. It was ineffective in *Klebsiella*, *Pasteurella*, *Pseudomonas*, and *Salmonella* infections.

Cross resistance has not been demonstrated with penicillin, erythromycin, triacetyleandomycin, chloramphenicol, novobiocin, streptomycin, or the tetracyclines. Staphylococci develop resistance to LINCOCIN in a slow, stepwise manner based on *in vitro*, serial subculture experiments. This pattern of resistance development is unlike that shown for streptomycin.

Clinical Absorption and Excretion—Administered intramuscularly, LINCOCIN Sterile Solution is very rapidly absorbed. In studies with dogs, peak serum levels were reached in from ten minutes to two hours with detectable levels for 16 to 24 hours. The concentration of LINCOCIN in the blood serum varies with the dose administered and with the individual animal. Levels are maintained above the *in vitro* minimum inhibitory concentration for most gram-positive organisms for six to eight hours following a therapeutic dose. Intravenous administration also provides very rapid absorption, but should be

administered with normal saline or 5% glucose as an intravenous drip infusion.

Administered orally to dogs, LINCOCIN was also rapidly absorbed with serum levels present within one-half hour; peak values were reached at two to four hours; and detectable levels persisted for 16 to 24 hours.

Tissue level studies indicate that bile is an important route of excretion. Significant levels of LINCOCIN have been demonstrated in the majority of body tissues. After a single oral administration of LINCOCIN to a dog, fecal excretion amounted to 77 percent of the dose; urinary excretion to 14 percent. After a single intramuscular injection, fecal excretion equaled 38 percent of the dose; and urinary excretion, 49 percent. Urinary excretion was essentially complete in less than 24 hours and fecal excretion by 48 hours after either route of administration. LINCOCIN has also been shown to be excreted in the milk of lactating cows, goats, rats, and women.

INDICATIONS

LINCOCIN products are indicated in infections caused by gram-positive organisms which are sensitive to its action, particularly streptococci and staphylococci. The drug has proven effective in eradicating causative organisms in most of the common upper respiratory tract infections, in septicemia, and in infections of the skin and adjoining tissues.

Systemic therapy with LINCOCIN has been shown to be of benefit in many animals with pustular dermatitis. As with all antibiotics, *in vitro* sensitivity studies should be performed before LINCOCIN is utilized as sole antibiotic therapy.

LINCOCIN has been demonstrated to be effective in the treatment of staphylococcal infections resistant to other antibiotics and sensitive to lincomycin. The drug may be administered in combination therapy with other antimicrobial agents when indicated.

No serious hypersensitivity reactions have been reported and many animals have received LINCOCIN repeatedly without developing evidence of hypersensitivity.

In dogs, LINCOCIN has demonstrated excellent efficacy in the treatment of upper respiratory infections and of skin diseases, particularly those caused by staphylococcus and streptococcus organisms. LINCOCIN has demonstrated efficacy even in some chronic conditions of long standing and in infections which have resisted treatment with other antibacterial agents.

Infections successfully treated with LINCOCIN include pustular dermatitis, abscesses, infected wounds (including bite and fight wounds), tonsillitis, laryngitis, metritis, and secondary bacterial infections associated with the canine distemper-hepatitis complex.

In cats, LINCOCIN has demonstrated efficacy in the treatment of localized infections, such as abscesses following fight wounds, pneumonitis, and feline rhinotracheitis.

Success in the treatment of viral diseases must be attributed to the control of susceptible secondary bacterial invaders rather than to any effect of LINCOCIN on the virus.

CONTRAINDICATIONS

As with all drugs, the use of LINCOCIN products is contraindicated in animals previously found to be hypersensitive to the drug.

LINCOCIN should not be given to animals with known preexisting monilial infections.

The following species are sensitive to the gastrointestinal effects of lincomycin: rabbits, hamsters, guinea pigs and horses. Therefore, the administration of LINCOCIN should be avoided in these species.

WARNING—Not for human use.

PRECAUTIONS

The use of antibiotics occasionally results in overgrowth of nonsusceptible organisms—particularly yeasts. Should superinfections occur, appropriate measures should be taken.

ADVERSE REACTIONS

Loose stools occasionally have been observed in dogs and cats on oral doses. Vomiting in cats has occasionally been reported following oral administration.

Intramuscularly and intravenously, LINCOCIN products have demonstrated excellent local tolerance with no reports of pain or inflammation following injection.

DOSAGE AND ADMINISTRATION

Oral: 10 mg per pound of body weight every 12 hours or 7 mg per pound every 8 hours.

Intramuscular: 10 mg per pound of body weight once a day or 5 mg per pound every 12 hours.

Intravenous: 5 to 10 mg per pound of body weight one or two times per day diluted with 5 percent glucose in water or normal saline and given as a drip infusion.

Treatment with LINCOCIN products may be continued for periods as long as 12 days if clinical judgment indicates.

As with any multi-dose vial, practice aseptic techniques in withdrawing each dose. Adequately clean and disinfect the vial closure prior to entry with a sterile needle and syringe.

HOW SUPPLIED

LINCOCIN products for veterinary use are available in the following dosage forms and strengths:

Tablets

100 mg: Each scored tablet contains lincomycin hydrochloride equivalent to lincomycin, 100 mg; supplied in bottles of 500; NDC 0009-0595-05.

200 mg: Each scored tablet contains lincomycin hydrochloride equivalent to lincomycin, 200 mg; supplied in bottles of 250; NDC 0009-0596-02.

500 mg: Each scored tablet contains lincomycin hydrochloride equivalent to lincomycin, 500 mg; supplied in bottles of 100; NDC 0009-0475-01.

NADA #33-887, Approved by FDA

AQUADROPS®

Each mL containing lincomycin hydrochloride equivalent to lincomycin, 50 mg; preserved with methylparaben 0.075%, propylparaben 0.025%, and sorbic acid 0.1%. Supplied in 20 mL bottles with graduated dropper; NDC 0009-0570-01. NADA#40-587, Approved by FDA.

Sterile Solution

Each mL containing lincomycin hydrochloride equivalent to lincomycin, 100 mg; also Benzyl Alcohol, 9.45 mg added as preservative. Supplied in 20 mL vials; NDC 0009-0617-01. NADA #34-025. Approved by FDA.

Store at controlled room temperature 20° to 25° C (68° to 77° F) [see USP].

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Lincocin Aquadrops and Sterile Solution Made by

Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

Lincocin Tablets Made in Canada for

Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

By **Patheon YM Inc.**

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