LINCOWAN FORTE PREMIX POWDER
(Lincomycin HCl)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

LINCOWAN FORTE PREMIX POWDER.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Kg Powder Contains:
Lincomycin HCl …….. 110gm

3. PHARMACEUTICAL FORM

Oral Powder.

4. CLINICAL INFORMATION

4.1. Target species

Poultry.

4.2. Indications for use specifying the target species

Chickens
Treatment and metaphylaxis of necrotic enteritis caused by *Clostridium perfringens*. Before using the product, the presence of the disease in the flock must be established.

4.3. Contraindications

Do not use in case of known hypersensitivity to the active substance or to any of the excipients. Do not use in case of known resistance to lincosamides. Do not administer or allow access to water containing lincomycin to horses, ruminants, hamsters, chinchillas and rabbits, as it may cause serious gastrointestinal disorders. Do not use if you have liver dysfunction.

4.4. Special warnings for each target species

The intake of medicated drinking water may be affected by the severity of the disease. If insufficient water intake is present.

The susceptibility of *Mycoplasma hyopneumoniae* to antimicrobial agents is difficult to test in vitro due to technical impediments. Furthermore, there is a lack of clinical breakpoints for both *M. hyopneumoniae* and *C. perfringens*. Where possible, therapy should be based on local (regional, herd) epidemiological information regarding the response of enzootic pneumonia/necrotic enteritis to lincomycin treatment.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should preferably be based on identification of the target pathogen and susceptibility testing of bacteria isolated from the animal. However, see also section
When using the veterinary medicinal product, official, national and regional regulations on the use of antimicrobial products must be observed. Use of the veterinary medicinal product deviating from the instructions given in the summary of product characteristics may increase the prevalence of bacteria resistant to lincomycin and may reduce the effectiveness of treatment with other lincosamides, macrolides and streptogramin B due to the potential for cross-resistance. Repeated or prolonged use should be avoided by improving farm management and hygiene practices.

Special precautions to be taken by the person administering the product to animals:

The product contains lincomycin and lactose monohydrate, which may cause allergic reactions in some individuals. People with known hypersensitivity to lincomycin or any other lincosamide or lactose monohydrate should avoid contact with the veterinary medicinal product.

Care must be taken not to raise and inhale the dust. Avoid contact with skin and eyes. Personal protective equipment consisting of approved dust masks (a disposable half-mask respirator compliant with European Standard EN 149 or a disposable reusable respirator compliant with European Standard EN 140 with an EN 143 filter), gloves, and safety glasses must be worn when handling and mixing the product. If respiratory symptoms occur after exposure, seek medical advice and show this warning.

In case of accidental exposure to skin, eyes, or mucous membranes, rinse the affected area thoroughly with plenty of water. If symptoms such as a rash or persistent eye irritation appear after exposure, seek medical advice immediately and show the package insert or label. Do not smoke, eat or drink while handling this product. Wash your hands and exposed skin immediately with soap and water.

Special precautions for environmental protection:

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

Allergic/hypersensitive reactions have occurred rarely.
The frequency of adverse reactions is defined using the following convention:

- **very common** (more than 1 in 10 animals treated with adverse reactions)
- **common** (more than 1 but less than 10 animals in 100 animals treated)
- **uncommon** (more than 1 but less than 10 animals in 1,000 animals treated)
- **rare** (more than 1 but less than 10 animals in 10,000 animals treated)
- **Very rare** (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7. Use during pregnancy and lactation or lay

Laboratory studies in rats have not shown any teratogenic effects, although fetotoxicity has been reported. The safety of the veterinary medicinal product has not been established

during pregnancy, lactation, or egg-laying in the target species. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

Antagonism between lincomycin and macrolides such as erythromycin and other bactericidal antibiotics is possible; therefore, concomitant use is not recommended due to competitive binding to the 50S ribosomal subunit of the bacterial cell. The bioavailability of lincomycin may be decreased in the presence of gastric antacids or activated charcoal, pectin or kaolin. Lincomycin may enhance the neuromuscular effects of anesthetics and muscle relaxants.

4.9. Dosage and administration route

To ensure correct dosing and avoid underdosing, body weight should be determined as accurately as possible. The intake of medicated water depends on the physiological and clinical conditions of the animals. To achieve the correct dosage, the lincomycin concentration must be adjusted accordingly. Water intake should be monitored frequently. Medicated water should be the animals' sole source of drinking water for the entire duration of treatment. After the end of the treatment period, the water supply system must be thoroughly cleaned to avoid the ingestion of sub-therapeutic amounts of the active ingredient.

Dose:
Chickens: Necrotic enteritis: 5 mg of lincomycin per kg of body weight (corresponding to 12.5 mg of product per kg of body weight) for 7 consecutive days.
The concentration to be used depends on the actual body weight and water consumption of the animals and can be calculated according to the following formula:

Dosage (mg of product per kg of body weight per day) x Average body weight (kg) of animals to be treated = ... mg of product per litre of drinking water

Average daily water intake (liter/animal)
It is recommended to use appropriately calibrated weighing equipment if partial packs are used. The daily amount should be added to the drinking water so that all the medicine is consumed within 24 hours. The medicated drinking water should be freshly prepared every 24 hours. No other source of drinking water should be available

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

A dose greater than 10 mg of lincomycin per kg of body weight can cause diarrhoea and loose stools.In case of accidental overdose, treatment should be discontinued and resumed at the recommended dose. There is no specific antidote, treatment is symptomatic.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

Chickens: Meat and offal: 5 days.
Not authorized for use in laying birds producing eggs for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use; Lincosamides.
ATCvet Code: **QJ01FF02**

5.1. Pharmacodynamics properties

Lincomycin is a lincosamide antibiotic derived from *Streptomyces lincolnensis* that inhibits protein synthesis. Lincomycin binds to the 50S subunit of the bacterial ribosome near the peptidyl transfer center and interferes with peptide chain elongation by causing premature dissociation of peptidyl-tRNA from the ribosome.

Lincomycin is active against some Gram-positive bacteria (*Clostridium perfringens*) and mycoplasmas (*Mycoplasma hyopneumoniae*).

While lincosamides are generally considered bacteriostatic agents, their activity depends on the organism's sensitivity and the antibiotic concentration. Lincomycin can be bactericidal or bacteriostatic. Lincomycin resistance is often conferred by plasmid-borne factors (*erm* genes) that encode methylases that modify the ribosomal binding site, often leading to cross-resistance to other antimicrobials in the macrolide, lincosamide, and streptogramin groups. However, the most common mechanism in mycoplasmas is alteration of the binding site through mutational events (chromosomal resistance). Resistance to lincomycin mediated by efflux pumps or inactivating enzymes has also been described. Complete cross-resistance between lincomycin and clindamycin is often present.

5.2. Pharmacokinetic information

Lincomycin crosses the intestinal barrier and is widely distributed to all tissues, especially the lungs and joints; the volume of distribution is approximately 1 liter. Lincomycin’s elimination half-life is greater than 3 hours. Approximately 50% of lincomycin is metabolized in the liver. Lincomycin undergoes enterohepatic circulation. Lincomycin is eliminated unchanged or as various metabolites in bile and urine. High concentrations of the active form are observed in the intestine.

Chickens were administered lincomycin hydrochloride in drinking water at a dose of approximately 34 mg/liter (5.1-6.6 mg/kg body weight) for seven days. Metabolites comprised more than 75% of the total liver residue. Unmetabolized lincomycin decreased with a slightly faster half-life (t1/2 = 5.8 hours) than the total residue. Lincomycin and an unknown metabolite comprised >50% of the muscle residue at zero hours. Excretion contained primarily unmetabolized lincomycin (60-85%) during treatment.

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients

Lactose monohydrate.

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after dilution or reconstitution according to instructions: 24 hours.

6.4. Special precautions for storage

Store below 25°C in a dry place.
Do not store in the refrigerator or freezer.
Protect from light and moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

- **For 5 kg:** Plain Milky white LDPE bag.
- **For 25 Kg:** Filled in Woven bag

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 022149

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 05-11-1998

10. DATE OF REVISION OF THE TEXT

17-02-2025