FLUMEVET C-50 POWDER

(Flumequine & Colistin Sulphate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

FLUMEVET C-50 POWDER.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Kg Contains:
Flumequine …… 500gm
Colistin Sulphate …….. 50gm

3. PHARMACEUTICAL FORM

Oral Powder.

4. CLINICAL INFORMATION

4.1. Target species

Poultry, Calves and Lambs

4.2. Indications for use specifying the target species

This broad-spectrum antibiotic is used for the prevention and treatment of gastrointestinal and respiratory bacterial infections in poultry, calves, and lambs. It is effective against Gram-positive and Gram-negative bacteria, including E. coli, Staphylococcus, Pasteurella, Salmonella, and Haemophilus.

4.3. Contraindications

Not Reported.

4.4. Special warnings for each target species

Not Reported.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Not Reported.

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

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 irrita-

tion 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)

Not Reported.

4.7. Use during pregnancy and lactation or lay

Not Reported.

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

Not Reported.

4.9. Dosage and administration route

Usage:
Orally Via drinking water.
Dosage:
For poultry: 50-100 g per 100- 200 liters of drinking water per day for 3-5 days.
Calves, lambs: 1 g per 6-8 kg daily live weight for 5 - 7 days
Rabbits: 1 g per 8 kg live weight daily for 3 - 6 days

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

Not Reported.

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:

Animals are slaughtered after 3 days of last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of Antibiotics.

5.1. Pharmacodynamics properties

Flumequine is a bactericidal antibacterial agent from the quinolone group. Its mechanism of action involves inhibiting DNA gyrase (Topoisomerase II), an enzyme crucial for the formation of the DNA helix. This disrupts the bacteria's ability to replicate and repair DNA, leading to cell death. Flumequine has a narrow spectrum of activity, acting primarily against Gram-negative bacteria. Resistance can develop through mutations in the GyrA subunit of DNA gyrase and, less frequently, in the ParC subunit (Topoisomerase IV).

Other resistance mechanisms involve the bacteria decreasing membrane permeability or increasing the active transport of the drug out of the cell.
Colistin sulfate is a polymyxin antibiotic that has a bactericidal effect against many Gram-negative bacteria. Its primary mechanism of action involves disrupting the integrity of the bacterial cell membrane. It is a cationic compound that binds to the negatively charged outer membrane of bacteria, displacing divalent cations like calcium and magnesium. This process disrupts the membrane structure, leading to leakage of essential intracellular contents and, ultimately, bacterial cell death. Colistin is considered a concentration-dependent antibiotic, meaning its effectiveness is linked to achieving a high drug concentration at the site of infection.

5.2. Pharmacokinetic information

Flumequine After oral administration, only about 10% of the flumequine dose is absorbed, with peak plasma concentrations reached within two hours. It is widely distributed in tissues and has a plasma protein binding of 74.5%. The absorbed drug is excreted primarily in the urine as both unchanged flumequine (40-60%) and an inactive glycoconjugated metabolite. A small amount is also excreted in the feces.
Colistin sulfate when administered orally to animals, colistin sulfate is very poorly absorbed from the gastrointestinal tract. This means that its effects are primarily localized to the digestive system, making it suitable for treating intestinal infections caused by susceptible Gram-negative bacteria. Due to its negligible absorption, systemic concentrations are very low, and the drug is excreted almost entirely unchanged in the feces. This poor bioavailability also minimizes the risk of systemic side effects and reduces the potential for drug residues in food-producing animals.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

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

6.2. 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.

6.3. 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.

6.4. Nature and composition of primary conditioning

For100gm & 500gm in Metalized Aluminium Foil Pouch

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.: 019914

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 03-10-1996

10. DATE OF REVISION OF THE TEXT

17-02-2025