

FLUSTIN LIQUID

(Flumequine & Colistin Sulphate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

FLUSTIN LIQUID

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:

Flumequine 20gm

Colistin Sulphate 2gm

3. PHARMACEUTICAL FORM

Oral Solution.

4. CLINICAL INFORMATION

4.1. Target species

Poultry (broiler chickens and turkeys).

4.2. Indications for use specifying the target species

Treatment of infections caused by microorganisms sensitive to flumequine such as:

- Poultry (broiler chickens and turkeys): colibacillosis, salmonellosis, pasteurellosis.
- Lambs: colibacillosis, septicaemia, pasteurellosis.
- Calves: Bronchopneumonia, colibacillary enteritis, neonatal diseases, salmonellosis

4.3. Contraindications

Do not use in animals with kidney or liver failure.

Do not use in cases of hypersensitivity to the active ingredient or any of the excipients.

Do not use in animals with a functioning rumen.

Do not use in laying birds (see section 3.7).

4.4. Special warnings for each target species

Do not use in laying birds whose eggs are intended for human consumption.

Water intake in animals may be modified as a result of the disease; in animals with poor appetite or reduced water consumption, administer an alternative parenteral treatment.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Good clinical practice requires basing treatment on identification and susceptibility testing of the target pathogen(s). If this is not possible, treatment should be based on epidemiological information and farm- or local (regional)-level knowledge of the susceptibility of the target pathogen(s).

The use of this veterinary medicinal product should be in accordance with official (national or regional) recommendations on the use of antimicrobials.

An antibiotic with the lowest risk of resistance selection (lowest AMEG category) should be used as first-line treatment, when susceptibility testing supports the efficacy of this approach.

Do not expose treated animals to the sun, due to the risk of photosensitization.

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

Flumequine may cause hypersensitivity (allergy) after inhalation, ingestion, or skin contact. Cross-hypersensitivity with other quinolones may occur.

People with known hypersensitivity to quinolones should avoid all contact with the medication.

To avoid exposure during the preparation and administration of the veterinary medicinal product, wear personal protective equipment consisting of coveralls, approved safety goggles, impermeable gloves (e.g. rubber or latex) and a disposable respirator mask complying with European Standard EN 149 or a non-disposable respirator mask complying with European Standard EN 140 with a filter complying with EN 143 when handling the veterinary medicinal product.

In case of accidental contact with eyes and skin, rinse thoroughly with water. If symptoms such as eye or skin irritation appear after exposure, consult a doctor immediately and show the package leaflet or label. Swelling of the face, lips, or eyes or difficulty breathing are more serious signs that require urgent medical attention.

Do not smoke, eat or drink while handling the medication.

Special precautions for environmental protection:

It does not proceed.

4.6. Adverse reactions (frequency and seriousness)

Poultry (broiler chickens and turkeys), cattle (calves) and sheep (lambs)

Uncommon (1 to 10 animals per 1,000 animals treated):	Photosensitivity Allergic skin reaction
Rare (1 to 10 animals per 10,000 animals treated):	Digestive disorders (vomiting, diarrhea)
Very rare (<1 animal per 10,000 animals treated, including isolated reports):	Nervous disorders (hyperexcitation)

4.7. Use during pregnancy and lactation or lay

Pregnancy and lactation:

- The safety of the veterinary medicinal product during pregnancy and lactation in sows has not been demonstrated.
- Use only according to the benefit/risk assessment carried out by the responsible veterinarian.
- **Birds in laying period:**
- Do not use in birds during the laying period and in the 4 weeks prior to the start of the laying period.

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

Do not administer simultaneously with trimethoprim.

4.9. Dosage and administration route

Oral route.

Dilute the required amount of medication in water; shake until a homogeneous solution is obtained and administer to the animals.

Poultry (chickens and turkeys): 12–24 mg of flumequine/kg body weight (equivalent to 1 ml/8–16 kg of body weight) and 2.80–3.66mg of Colistin Sulphate/kg body weight (equivalent to 1 ml-1.46ml/8–16 kg of body weight) per day, for 3–5 consecutive days. The weight of the animals must be determined as accurately as possible to ensure correct dosing. If animals are to be treated collectively, they should be grouped by body weight, and dosing should be based on their weight.

If there is no improvement within three days of starting treatment, review the diagnosis and, if necessary, change therapy.

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

In cases of overdose, digestive or nervous disorders may occur, which subside when the medication is discontinued.

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:

Meat: Broiler chickens: 2 days

Turkeys: 10 days

Eggs:

Its use is not authorized in birds whose eggs are used for human consumption.

Do not use within 4 weeks of laying.

5. PHARMACOLOGICAL PROPERTIES

ATC vet code: **QJ01MB07**

5.1. Pharmacodynamics properties

Flumequine is an antibacterial agent belonging to the quinolone group, with bactericidal activity that acts by inhibiting DNA gyrase, an enzyme involved in the formation of the DNA helix.

It has a narrow spectrum of activity that essentially covers Gram-negative bacteria.

Resistance to flumequine, as with other quinolones, occurs due to the alteration of DNA gyrase (Topoisomerase II) through mutation of the Gyr-A subunit and, less frequently, through mutation of the ParC subunit (Topoisomerase IV).

Other resistance mechanisms appear when the bacteria decreases the permeability of its membrane, thus preventing the passage of the antimicrobial or increasing the active transport of the compound outside the cell.

Cross-resistance between quinolone class antimicrobials is common.

Colistin Sulphate 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, 10% of the dose is absorbed, with peak plasma concentrations reached after 2 hours.

It is widely distributed in tissues.

Plasma protein binding is 74.5%.

Unchanged flumequine and its hydroxylated metabolite, which is less active, are found in blood.

40–60% of the absorbed dose is excreted as unchanged drug in urine, and the remainder as the inactive glycoconjugated metabolite.

A small portion is excreted in feces.

Colistin Sulphate when administered orally to animals, colistin Sulphate 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 Excipients

Benzyl alcohol (E-519)

6.2 Incompatibilities

With acidic products, because they make it difficult to dissolve in water or lead to precipitation of flumequine.

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 first opening the container: use within 28 days, do not store.

Shelf life after dissolving according to instructions: 24 hours.

6.4. Special precautions for storage

Store below 25°C & in dry place

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

The product is available in various pack sizes:

For 100ml, 200ml & 500ml: HDPE bottles with induction-sealed caps

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.: 035058

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 13-12-2004

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:



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