FLO-X POWDER

(Florfenicol, Neomycin Sulphate, Oxytetracycline HCL)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

FLO-X POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:
Florfenicol…….100mg
Neomycin Sulphate……...150mg
Oxytetracycline HCL……300mg

3. PHARMACEUTICAL FORM

Powder for oral solution.

4. CLINICAL INFORMATION

4.1. Target species

Poultry.

4.2. Indications for use specifying the target species

Poultry:
- Treatment of gastrointestinal infections caused by germs sensitive to florfenicol, oxytetracycline and neomycin.

4.3. Contraindications

Do not use in case of: -
History of hypersensitivity to Fenicols, tetracyclines and/or aminoglycosides.
Renal failure.
Known resistance to tetracyclines and/or aminoglycosides.

4.4. Special warnings for each target species

This powder for oral solution is intended exclusively for the target species indicated in the "Target species" section.

4.5. Special precautions for use

Special precautions for safe use in the target species:

This powder for oral solution is intended to be dissolved in milk, liquid food or drinking water and cannot be used as is.

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

Do not handle this product if you have a known allergy to tetracyclines or aminoglycosides. Hypersensitivity to neomycin and other aminoglycosides may be cross-related. Allergic reactions to these substances may be serious. In case of hypersensitivity, avoid any contact with the product. Handle this product with recommended precautions to avoid any risk of exposure. Wearing a mask, goggles and protective gloves is recommended when preparing the solution. Avoid breathing dust and avoid contact with skin and eyes.
If skin erythema appears, seek medical advice. If swelling of the face, lips, eyes or breathing difficulties occur, consult a doctor immediately.
In case of accidental projection into the eyes, rinse thoroughly with clean water. Wash hands after using the product.

iii) Other precautions
None.

4.6. Adverse reactions (frequency and seriousness)

As with all tetracyclines, oxytetracycline may cause adverse effects such as gastrointestinal disturbances and, less commonly, allergic and photosensitivity reactions.

4.7. Use during pregnancy and lactation or lay

Oxytetracycline has shown no evidence of embryotoxicity or teratogenicity in laboratory animals.
In mammals, oxytetracycline crosses the placental barrier, causing tooth discoloration and slowed fetal growth.
Tetracyclines are found in breast milk. The safety of the product has not been evaluated in pregnant or lactating animals. Use of the product in pregnant or lactating animals should be subject to a benefit/risk assessment by the veterinarian.

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

Divalent or trivalent cations (Mg, Fe, Al, Ca) can chelate tetracyclines.
Tetracyclines should not be administered with antacids, aluminum gels, vitamin or mineral preparations because insoluble complexes are formed, which decrease the absorption of the antibiotic.

4.9. Dosage and administration route

Oral route.
Poultry, 1gm to 3-4 liters of drinking water for 3-5 days.
The amount of medicated drinking water, milk or liquid feed consumed by animals depends on their physiological and clinical condition. In order to obtain the recommended dose of neomycin and oxytetracycline per kg of body weight, the amount of powder to be diluted in the liquid must be adjusted accordingly.

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

See section “Undesirable effects”.
4.11. Special restrictions on use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to limit the risk of development of resistance

Not applicable.

4.12. Withdrawal period:

Poultry: Meat and offal: 14 days. Eggs: zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: intestinal anti-infectives, neomycin in combination.
ATCvet code. **QA07AA51**

5.1. Pharmacodynamics properties

Neomycin is an aminoglycoside antibiotic, obtained from Streptomyces fradiae. Its spectrum of activity covers Gram-positive germs, particularly Staphylococci and less actively Streptococci, and Gram-negative germs, particularly Escherichia coli. Neomycin binds to the 30S subunit of the bacterial ribosome, disrupting the reading of the constitutive code of messenger RNA, and ultimately bacterial protein synthesis. At high concentrations, aminoglycosides have been shown to damage the bacterial cell wall, adding bactericidal to bacteriostatic properties.
Oxytetracycline binds reversibly to the receptors of the 30 S ribosomal moiety, leading to a blockade of the binding of aminoacyl-tRNA to the corresponding site of the ribosome-mRNA complex. This results in an inhibition of protein synthesis and thus a cessation of the growth of the bacterial culture. Oxytetracycline has a mainly bacteriostatic activity.
The bacteriostatic activity of oxytetracycline involves penetration of the substance into the bacterial cell. Penetration of oxytetracycline occurs both by passive and active diffusion. The main possible mode of resistance is related to the possible presence of an R factor, responsible for a decrease in the active transport of oxytetracycline. Oxytetracycline is a broad-spectrum antibiotic. It is active primarily against Gram-positive and Gram-negative, aerobic and anaerobic microorganisms, as well as Mycoplasma, Chlamidiae, and Rickettsiae. Acquired resistance to oxytetracycline has been reported. Such resistance is usually plasmid-mediated. Cross-resistance to other tetracyclines is possible. Continued treatment with low doses of oxytetracycline may also result in increased resistance to other antibiotics.
Florfenicol is a potent, broad-spectrum synthetic antibiotic in the phenicol class, specifically developed for veterinary use. It is a structural analogue of thiamphenicol, but it contains a fluorine atom that makes it highly resistant to the bacterial enzymes that typically deactivate older drugs like chloramphenicol. This modification allows it to remain effective against a wide variety of resistant Gram-positive and Gram-negative bacteria.
The primary mechanism of action is the inhibition of bacterial protein synthesis. Florfenicol enters the bacterial cell and binds specifically to the 50S subunit of the ribosome. By attaching to this site, it blocks the enzyme peptidyl transferase, preventing the attachment of amino acids to the growing peptide chain. Without the ability to produce these essential proteins, the bacteria can no longer grow or replicate.
In terms of antibacterial activity, florfenicol is generally classified as bacteriostatic (inhibiting growth), but it is uniquely bactericidal (killing the bacteria) against key respiratory pathogens like *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. Because it reaches high concentrations in lung tissue and lacks the specific chemical group (p-nitro group) associated with bone marrow toxicity in humans, it is a primary choice for treating Bovine (BRD).

5.2. Pharmacokinetic information

Neomycin is very poorly absorbed from the gastrointestinal tract. In plasma and tissues, neomycin concentrations are very low. It is therefore present in significant quantities and persistently in the different sections of the digestive tract. Neomycin is almost exclusively eliminated in the feces after oral administration.

For most species, oxytetracycline is rapidly (2 to 4 hours) absorbed after oral administration in fasted animals and its bioavailability is between 60% and 80%. This bioavailability may be reduced in the presence of food in the stomach because oxytetracycline forms insoluble chelates with the divalent or trivalent cations (Mg, Fe, Al, Ca) they contain.
Oxytetracycline binds to plasma proteins to varying degrees depending on the species (20—40%). Its distribution is broad. Oxytetracycline diffuses throughout the body, with the highest concentrations found in the kidneys, liver, spleen, and lungs. Oxytetracycline crosses the placental barrier. Oxytetracycline is eliminated unchanged, mainly via urine. It is also excreted via biliary tract but a large proportion of oxytetracycline is reabsorbed by the small intestine (enterohepatic cycle).
Florfenicol is characterized by rapid and extensive absorption across most veterinary species. Whether administered orally or via injection (IM/SC), it typically reaches peak plasma concentrations within 1 to 3 hours. Its high bioavailability often exceeding 80% ensures that a significant portion of the dose is available to combat systemic infections.
Due to its lipophilic nature, the drug achieves wide tissue distribution. It effectively penetrates the lungs, liver, and kidneys, and is one of the few antibiotics capable of crossing the blood-brain barrier to reach the central nervous system. This allows it to maintain therapeutic levels at the site of infection, particularly in respiratory and neurological cases.
The metabolism and excretion of florfenicol occur primarily through the liver and kidneys. While it is partially metabolized into florfenicol amine, a large amount of the drug is excreted in its active form through the urine. Its elimination half-life varies by species longer in cattle and shorter in poultry which directly influences dosing schedules and the required withdrawal periods for food safety.

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 first opening the container: use immediately, do not store.

6.2. 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.

6.3. Nature and composition of primary conditioning

Metalized Aluminum Foil pouch for
100gm, 250gm, 500gm, 1000gm

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.: 133440

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 06-01-2026

10. DATE OF REVISION OF THE TEXT

17-03-2026