

COLIMOX POWDER

(Amoxicillin Sodium & Colistin Sulphate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

COLIMOX POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gm Contains:

Amoxicillin Sodium (base) 100mg

Colistin Sulphate 500,000 IU

3. PHARMACEUTICAL FORM

Oral powder

4. CLINICAL INFORMATION

4.1. Target species

Poultry

4.2. Indications for use specifying the target species

The product is recommended in adeno-coli syndrome, streptococcal infections, staphylococcal infections, gastrointestinal infections in pigeons that are not intended for human consumption.

4.3. Contraindications

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

4.4. Special warnings for each target species

None exist.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Due to variability (over time, geographically) in the susceptibility of bacteria in the case of using the product, it is recommended to take bacteriological samples and perform susceptibility tests for microorganisms isolated from diseased animals, if possible. If this is not possible, the therapy should be based on local epidemiological information (region, farm) regarding the susceptibility of the target bacteria.

Official and local antimicrobial policies should be taken into account when using the product.

Off-label use of the product contrary to the instructions in the SPC may increase the prevalence of bacteria resistant to the active substances and may decrease the effectiveness of treatment due to the possibility of cross-resistance.

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

After using the product, wash hands thoroughly. In case of contact with eyes, rinse well with water and seek medical advice if irritation persists. Avoid direct contact of the product with skin and eyes during product handling. Wear personal protective equipment: gloves and eye protection when preparing and handling the product.

In case of accidental ingestion, seek immediate medical advice and show the package leaflet or the label to the physician. People with known hypersensitivity to the active substances should handle the product with caution.

4.6. Adverse reactions (frequency and seriousness)

Not known at the recommended dose.

4.7. Use during pregnancy and lactation or lay

Not applicable.

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

Not known.

4.9. Dosage and administration route

The recommended dose is 5.5 g of product per 2 liters of water, for 7 days.
The route of administration is oral, in drinking water.

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

Do not exceed the recommended dose.

4.11 Specific restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products to reduce the risk of development of resistance

Not applicable

4.11. Withdrawal period:

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, 2 penicillins in combination with other antibacterials

Veterinary medicinal product code ATC: **QJ01RA01**

5.1. Pharmacodynamics properties

Amoxicillin is a bactericidal antibiotic from the beta-lactam class. It acts by inhibiting the synthesis of the bacterial cell wall. It is not resistant to the action of beta-lactamases, which can hydrolyze the molecules in the beta-lactam structure, making the antibiotic action inactive. It has no irritant action on the intestinal mucosa and has very good bioavailability. It acts by inactivating bacterial enzymes.

Colistin sulfate is an antibiotic from the polymyxin class, being a mixture of polypeptide antibiotics colistin A and B. It is active against Gram-negative bacteria and is used as a polypeptide antibiotic. It has a potent bactericidal effect by degrading the phospholipids of the bacterial cell wall.

5.2 Pharmacokinetic information

Amoxicillin has both local and systemic action. After oral administration, amoxicillin is rapidly absorbed and then widely distributed in tissues and fluids. It is then eliminated mainly via urine.

Amoxicillin has efficient action against important Gram-negative bacteria (*E. coli*, *Salmonella* spp., *Haemophilus* spp.) and positive bacteria (*Streptococcus* spp., *Clostridium* spp.).

Excretion is via the renal route.

Colistin sulfate is not absorbed in the small intestine when administered orally, it diffuses only in the gastrointestinal tract and is eliminated in the feces. Colistin has only a local, gastrointestinal action. After oral administration, colistin does not distribute into fluids and tissues and is eliminated in the feces. It has bactericidal action against a large number of Gram-negative bacteria and little or no action against Gram-positive bacteria. Colistin is found in high concentrations in the gastrointestinal tract, especially in the cecum and colon. 40% of colistin remains in the gastrointestinal contents and 60% is found bound to the phospholipids and lipopolysaccharides of the Gram-negative bacterial wall.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Dextrose 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 according to instructions: 24 hours.

Shelf life after dilution in drinking water: use immediately.

6.4. Special precautions for storage

Store below 25°C.

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

Plastic Jar Belgian style with Orange Cap for, 200gm, 500gm, 1 Kg & 2.5 Kg

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

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived
from such products, in accordance with local requirements and national collection sys-
tems applicable to the veterinary medicinal product concerned.
Treated animals should be kept in shelters throughout the treatment period and their
droppings should be collected and NOT used for soil fertilization.

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.: 054000

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 31-03-2009

10. DATE OF REVISION OF THE TEXT

17-08-2025

MANUFACTURED BY:



NAWAN
LABORATORIES (PVT) LTD.

136, Sector 15, Korangi Industrial
Area, Karachi-74900, Pakistan.