COLIMOX INJECTION
(Amoxicillin Trihydrate, Colistin Sulphate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

COLIMOX INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Amoxicillin (as Trihydrate) ……. 10gm
Colistin (as Sulphate) …… 25MIU

3. PHARMACEUTICAL FORM

Suspension for Injection

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Goat & Horse.

4.2. Indications for use specifying the target species

Colimox injectable suspension is indicated in cattle, sheep, goats, and horses in the treatment of infections affecting the gastrointestinal, bronchopulmonary, urinary and skin systems, caused by Gram positive and Gram-negative microorganisms sensitive to the amoxicillin-colistin combination.

4.3. Contraindications

Do not use in animals with known hypersensitivity to amoxicillin or colistin.
Colimox injectable suspension is contraindicated in animals suffering from degenerative kidney diseases.

4.4. Special warnings for each target species

When performing the injection, use normal aseptic procedures. In the case of heavy animals for which the inoculum volume is high, it is advisable to divide the injection into two or more points. Not permitted for use in equines producing milk for human consumption.

4.5. Special precautions for use

Special precautions for safe use in the target species:

The product should be used based on the results of the antibiogram. If this is not possible, therapy should be based on local (regional or farm level) epidemiological information on the susceptibility of the target bacteria.

Use of the product deviating from the instructions provided may increase the prevalence of bacteria resistant to amoxicillin or colistin and may reduce the effectiveness of treatments with other antibacterial agents due to the potential for cross-resistance. Repeated or prolonged use should be avoided by improving management practices and through cleaning and disinfection. Particular attention must be paid to improving husbandry practices to avoid any stress conditions.

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

People with known hypersensitivity to the active substances should avoid contact with the veterinary medicinal product.
Avoid contact with eyes, skin, and mucous membranes.
Wash hands thoroughly after handling the product.
Keep out of reach of children.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

In rare cases, allergic reactions are possible. Soreness and hardening at the injection site may occur.

4.7. Use during pregnancy and lactation or lay

Use only in accordance with the benefit/risk assessment by the responsible veterinarian. Not permitted for use in animals producing milk or eggs for human consumption.

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

None known.

4.9. Dosage and administration route

Shake the bottle vigorously before use.
Cattle, sheep, goats & horses:
10 ml/100 kg bw per day (equivalent to 10 mg/kg bw of amoxicillin and 25,000 IU/kg bw of colistin sulphate per day).

To avoid over/underdosing, body weight should be determined as accurately as possible.

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

In the target species, at the therapeutic dose, the drug was found to be well tolerated.
Colistin overdose may cause renal failure with tubular necrosis: in these cases, discontinue treatment immediately. Do not exceed the indicated dosage.

4.11. Special restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products, in order to limit the risk of development of resistance

Administration under the control or supervision of the veterinarian

4.12. Withdrawal period:

Meat and offal:
Cattle, Sheep, goats: 28 days

Not permitted for use in equines producing milk for human consumption.

Not permitted for use in animals producing milk or eggs for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials

ATCvet code: **QJ01RA01**

5.1. Pharmacodynamics properties

Colimox is a combination of two antibiotics, amoxicillin and colistin. Amoxicillin, a semisynthetic penicillin active against Gram-positive and Gram-negative bacteria, acts by inhibiting [1] the synthesis of the bacterial wall.
Colistin is a polymyxin belonging to the family of cyclic polypeptides. It is active electively against Gram-negative microorganisms such as *Bordetella spp.*, *E. coli*, *Enterobacter aerogenes*, *Haemophilus spp.*, *Ornithobacterium rhinotracheale*, *Pasteurella spp.*, *Pseudomonas spp.*, *Salmonella spp.*, *Shigella spp.*, while it is poorly effective against Gram-positive organisms. Colistin acts by disorganizing the cell membrane with leakage of intracellular materials. The phenomenon of resistance, not completely known, however, seems rare. The MIC90 of the amoxicillin/colistin combination against the main pathogenic microorganisms of turkey are as follows:

BACTERIAL SPECIES	**MIC90 (µg/ml) amoxicillin/colistin**
Clostridium perfringens	0,975/0,097
Escherichia coli	1,95/0,195
Ornithobacterium rhinotracheale	0,487/0,048
Pasteurella multocida	0,975/0,097
Staphylococcus aureus	1,95/0,195

5.2 Pharmacokinetic information

Amoxicillin is stable in an acid environment and has a gastrointestinal absorption greater than 80% of the administered dose; parenterally, absorption is rapid and complete. It is bound to plasma proteins for about 15% of the amount present in the blood. It diffuses widely and rapidly, allowing to obtain blood and tissue concentrations higher than the average MIC. It has a high pulmonary tropism, reaching a concentration in bronchial mucus equal to twice the blood concentration; bacterial lysis is much faster than that obtained with ampicillin. It is non-toxic. It is eliminated in active form mainly through the urine.

Colistin, stable in an acidic environment (pH between 3 and 6), following oral administration, in the form of sulphate is not absorbed from the gastrointestinal tract, exerting only a local antibacterial action and therefore allowing a targeted therapy at the level of the gastrointestinal tract, where infections are normally sustained by Gram-negative microorganisms. When administered parenterally, colistin is rapidly absorbed and diffuses readily, reaching tissue levels that are higher and more prolonged than those in blood. Colistin is a polymyxin belonging to the family of cyclic polypeptides. It is active electively against Gram-negative microorganisms such as Bordetella spp., E. coli, Enterobacter aerogenes, Haemophilus spp., Ornithobacterium rhinotracheale, Pasteurella spp., Pseudomonas spp., Salmonella spp., Shigella spp., while it is poorly effective against Grampositive

organisms. Not permitted for use in animals producing milk or eggs for human consumption. The oral colistin-amoxicillin combination has an additive effect and allows, due to the two different pharmacokinetics of the active ingredients, to simultaneously perform a specific therapy of the gastrointestinal tract by colistin (which is not enteroabsorbed) and a systemic therapy, in particular of the respiratory, urinary and integumental systems by amoxicillin (which is enteroabsorbed). The same combination, used parenterally, allows a systemic therapy performed with both active ingredients, guaranteeing a greater possibility of success due to the overcoming of any resistance, mainly due to Gram-positives.

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 in a cool, dry place.
Protect from light.
Store below 25°C.
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

30ml, 50ml & 100ml in amber color vials. The vials are closed with bromobutyl rubber stoppers and sealed with aluminum flip off seal.

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 systems 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.: 020804

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 20-01-1998

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
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