AMOVET 50% POWDER
(Amoxicillin Trihydrate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AMOVET 50% POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram Contains:
Amoxicillin Trihydrate…500mg

3. PHARMACEUTICAL FORM

Oral powder

4. CLINICAL INFORMATION

4.1. Target species

Poultry (broiler chicken, turkey and duck)

4.2. Indications for use specifying the target species

Broiler chickens, turkeys and ducks: For the treatment of pasteurellosis and colibacillosis, caused by strains sensitive to amoxicillin.

4.3. Contraindications

Do not use in case of hypersensitivity to penicillins. Do not administer orally to rabbits, and hamsters since amoxicillin, like all aminopenicillins, has a significant action on the cecal bacterial population.
Do not use in equines since amoxicillin, like all aminopenicillins, has a significant action on cecal bacterial population. Orally, do not use in animals with a functional rumen.

4.4. Special warnings for each target species

Not permitted for use in laying birds whose eggs are intended for human consumption. Do not use in the 4 weeks prior to the beginning of the laying period or during laying.

4.5. Special precautions for use

Special precautions for safe use in the target species:

In any infectious process, bacteriological confirmation of the diagnosis and the performance of a sensitivity test of the bacteria causing the process are recommended. It is advisable to use the prepared product within the first 24 hours, discarding any unconsumed amount.

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

Penicillins and cephalosporins cause hypersensitivity (allergy) reactions following injection, inhalation, ingestion, or skin contact. Cross-hypersensitivity reactions have been observed between cephalosporins and penicillins.

- People with known hypersensitivity to penicillins and/or cephalosporins should avoid all contact with the veterinary medicinal product.
- Handle the product carefully to avoid inhaling dust as well as contact with skin and eyes when adding it to water, taking specific precautions:
    - Take appropriate measures to prevent the spread of dust when adding the product to drinking water.
    - Use personal protective equipment consisting of a dust mask (in accordance with EN140FFP1), gloves, and overalls and approved safety glasses when handling the veterinary medicinal product.
    - Avoid contact with skin and eyes. In case of contact, wash thoroughly with clear water.
    - Do not smoke, eat or drink while handling the product.
- If symptoms such as a rash appear after exposure, seek medical attention and present these warnings. Swelling of the face, lips or eyes or difficulty breathing are more serious signs that require urgent medical attention.

Special precautions for environmental protection

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

Hypersensitivity reactions whose severity can vary from simple hives to anaphylactic shock.
Gastrointestinal symptoms (vomiting, diarrhea).
Suprainfections by non-sensitive germs after prolonged use.

4.7. Use during pregnancy and lactation or lay

Laboratory studies carried out on rats and mice have not demonstrated teratogenic, toxic to the fetus or toxic to the mother effects. The safety of the veterinary medicinal product has not been established in pregnant or lactating sows; use only according to the benefit/risk assessment by the responsible veterinarian.

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

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

Do not use simultaneously with neomycin as it blocks the absorption of oral penicillins.
Do not use in conjunction with antibiotics that inhibit bacterial protein synthesis as they may antagonize the bactericidal action of penicillins.
Do not administer with bacteriostatic antibiotics.

4.9. Dosage and administration route

Oral route, through drinking water. Medicated water should be renewed every 24 hours.

Broiler chickens: 15 mg of amoxicillin/kg of live weight every 24 hours, the total duration of treatment being 5 days.

Broiler ducks: 20 mg amoxicillin/kg body weight every 24 hours for 3 days.
Broiler turkeys: 15 to 20 mg amoxicillin/kg body weight every 24 hours for 5 days.
Calculate the quantity of this product (g) to be added to the drinking water tank using the following formula:
(Number of animals x average weight of animals Kg x / 25 (for 20 mg/kg) or 33 (for 15 mg/kg)
Measure the resulting quantity with the standard equipment available.

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

They have not been described.
Amoxicillin has a wide margin of safety.

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

4.12. Withdrawal period:

Chickens: 1 day Turkeys: 5 days Ducks: 7 days
Its use is not authorized in laying birds whose eggs are used for human consumption.
Do not use within 4 weeks prior to the start of lay or during lay

5. PHARMACOLOGICAL PROPERTIES

Amoxicillin is a broad-spectrum beta-lactam antibiotic belonging to the aminopenicillin group. Chemically it is similar to ampicillin.

Pharmacotherapeutic group: Beta-lactam antibiotics. Broad-spectrum penicillins.
ATCvet code: **QJ01CA04.**

It has bactericidal action and acts against Gram-positive and Gram-negative microorganisms, inhibiting the biosynthesis and repair of the bacterial mucopeptidic wall. It is a semi-synthetic penicillin susceptible to the action of beta-lactamases.

5.1. Pharmacodynamics properties

- **Mechanism of action**

•The mechanism of amoxicillin's antibacterial action consists in the inhibition of the biochemical processes of bacterial cell wall synthesis, through a selective and irreversible blockage of various enzymes involved in such processes, mainly transpeptidases, endopeptidases and carboxypeptidases. The inadequate formation of the bacterial cell wall in susceptible species produces an osmotic imbalance that particularly affects bacteria in the growth phase (during which the processes of bacterial cell wall synthesis are especially important), which ultimately leads to lysis of the bacterial cell.

- **Spectrum of action**
- Species considered sensitive to amoxicillin include:
- Gram-positive bacteria
- *Streptococcus suis*

•Gram-negative bacteria:

- *Pasteurella* spp.
- *Escherichia coli*

•On the other hand, bacteria that generally show resistance to amoxicillin are:

•Penicilliase-producing staphylococci.
•Some enterobacteria such as *Klebsiella* spp., *Enterobacter* spp., *Proteus* spp. and other Gram-negative bacteria such as *Pseudomonas aeruginosa*.
•The main mechanism of bacterial resistance to amoxicillin is the production of beta-lactamases, enzymes that cause the inactivation of the antibacterial agent by hydrolysis of the beta-lactam ring, thus obtaining penicilloic acid, a stable but inactive compound. Bacterial beta-lactamases can be acquired through plasmids or be constitutive (chromosomal).
These beta-lactamases are exocellular in Gram-positive bacteria (Staphylococcus aureus) while they are located in the periplasmic space in Gram-negative bacteria.

- Gram-positive bacteria are capable of producing beta-lactamases in large quantities and secreting them into their environment. These enzymes are encoded in plasmids that can be transferred by phages to other bacteria.
- Gram-negative bacteria produce different types of beta-lactamases that remain localized in the periplasmic space. These are encoded both in the chromosome and in plasmids.
- There is complete cross-resistance between amoxicillin and other penicillins, in particular other aminopenicillins (ampicillin).
- Critical concentrations (breakpoints) for sensitivity (S) and resistance (R): in µg/ml: (Source: NCCLS 2000)

5.2 Pharmacokinetic information

• **Generalities:** Oral absorption of amoxicillin is independent of food intake and peak plasma concentrations are rapidly reached in most animal species between 1 and 2 hours after administration of the product.
• Amoxicillin is poorly bound to plasma proteins and rapidly diffuses into most body fluids and tissues. Amoxicillin is distributed primarily in the extracellular compartment. Its distribution into tissues is facilitated by its low plasma protein binding.
•The metabolism of amoxicillin is limited to the opening of the beta-lactam ring by hydrolysis, leading to the release of inactive penicilloic acid (20%). Biotransformations take place in the liver.
•The major route of elimination for amoxicillin is renal in active form. It is also excreted in small amounts in milk and bile.

• **CHICKENS:** Oral administration has a bioavailability of around 67%, reaching significant levels in the blood within one hour. It is distributed well and rapidly throughout the body, with little binding to plasma proteins (17–20%). Amoxicillin is well distributed to tissues by IV route with a volume of distribution of 0.9 L/kg. It is eliminated fairly rapidly, with a clearance of 0.6 L/h/kg and a plasma elimination half-life (t) of one hour.

6. PHARMACEUTICAL INFORMATION

6.1. List of Excipient

Anhydrous citric acid

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.

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

For 1kg: Plastic Jar Belgian style with Orange Cap
For 500gm: Metalized Aluminium foil for 500gm

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.: 118397

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 07-09-2023

10. DATE OF REVISION OF THE TEXT

17-08-2025