AMOVET 20% INJECTION
(Amoxicillin Trihydrate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AMOVET 20% INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Amoxicillin as Trihydrate……...200mg

3. PHARMACEUTICAL FORM

Suspension for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Goats, Dogs and Cats

4.2. Indications for use specifying the target species

Diseases caused by germs sensitive to amoxicillin.
Treatment of respiratory infections due to Gram-positive bacteria or Pasteurella

4.3. Contraindications

- Do not use in animals with hypersensitivity to beta-lactams.
- Do not administer to rabbits, hamsters or gerbils.
- The use of the veterinary medicinal product is contraindicated when resistance to amoxicillin is known.
- Do not use in animals with severe renal insufficiency accompanied by anuria or oliguria.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Improper use of the veterinary medicinal product may increase the prevalence of bacterial resistance to amoxicillin and may decrease its effectiveness.

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

• Penicillins and cephalosporins can cause hypersensitivity (allergy) reactions after injection, inhalation, ingestion, or skin contact. This hypersensitivity to penicillins can lead to cross-reactions with cephalosporins, and vice versa. These hypersensitivity reactions can occasionally be severe.
• Do not handle this veterinary medicinal product if you know you are sensitized or if you have been advised not to come into contact with this type of molecule.
• In case of accidental skin or eye contact, rinse immediately and thoroughly with water.
• If symptoms occur after exposure (skin redness), seek medical advice immediately and show the package leaflet or label to the doctor. Swelling of the face, lips, or eyes, or difficulty breathing are serious signs and require urgent medical treatment.

Special precautions for environmental protection

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

Very rare (< 1 animal / 10,000 animals treated, including isolated cases)	) Hypersensitivity reaction[1], Allergic reaction[1], Anaphylaxis[1]

[1]In goats the frequency of these reactions is undetermined (cannot be estimated on the basis of available data).

It is important to report adverse reactions. Reporting allows for continuous monitoring of the safety of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, either to the marketing authorisation holder or to the national competent authority via the national reporting system. See the package leaflet for the respective contact details.

4.7. Use during pregnancy and lactation or lay

The safety of the specialty has not been evaluated in the target species during pregnancy
Gestation: Studies in laboratory animals have not shown any teratogenic, embryotoxic or maternotoxic effects of amoxicillin.
The use of the veterinary medicinal product in pregnant females should only be carried out after an assessment of the benefit/risk ratio established by the responsible veterinarian.

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

The bactericidal effect of amoxicillin is neutralized by the simultaneous use of molecules with bacteriostatic action (macrolides, sulfonamides and tetracyclines). Such a combination will nevertheless have a bacteriostatic effect.

4.9. Dosage and administration route

Intramuscular or subcutaneous administration.
Recommended doses:
Calves, cattle, Sheep and Goats: 1 ml/13 kg body weight, and the dose can be repeated after 48 hours. Do not inject more than 20 ml at one site.
Dogs and cats: 1ml/13 kg body weight

To calculate the correct dose, the body weight should be determined as accurately as possible in order not to administer lower doses as necessary.
Shake the vial well before use.

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

No side effects were observed at a dose corresponding to 5 times the therapeutic dose, with the exception, in a limited number of animals, of a slight local reaction at the injection site, transient, reversible without treatment and without consequences for the animal.

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:

Meat and Offal: 14 Days
Milk: 4 Days
Dog & Cat: Not Applicable

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: **QJ01CA04.**

5.1. Pharmacodynamics properties

•The structure of amoxicillin includes the beta-lactam ring and the thiazolidine ring common to all penicillins. Beta-lactams prevent the formation of the bacterial cell wall by interfering with the final stage of peptidoglycan synthesis. They inhibit the activity of transpeptidases that catalyze the polymerization of glycopeptide units, which make up the bacterial cell wall. They have a bactericidal action only on growing cells.
•The activity is mainly exerted against Gram-positive bacteria, but some Gram-negative bacteria, in particular Pasteurella multocida and Mannheimia haemolytica, are also sensitive to the bactericidal effect of amoxicillin.

• Amoxicillin is susceptible to destruction by beta-lactamases produced by some strains.

5.2 Pharmacokinetic information

• After intramuscular administration of a dose of 15 mg/kg, amoxicillin is well absorbed with a systemic bioavailability of between 60 and 100%. Peak plasma concentrations of between 1.5 and 4.5 µg/mL depending on the species are observed 1.5 to 3 hours after administration.
• After repeated administration (2 injections 48 hours apart), the pharmacokinetic parameters remain stable and no accumulation phenomenon is observed. Plasma concentrations are maintained above the MIC90 for more than 32 hours after the first injection and up to 36 hours after the second injection.
• Amoxicillin is primarily eliminated in active form by the kidney.

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 within 28 days, do not store.

6.2. Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Shake well before use.
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

Cardboard box with glass injection vial (s).
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 100ml

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.: 118396

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 07-09-2023

10. DATE OF REVISION OF THE TEXT

17-02-2025