Amovet-GT Injection
(Amoxicillin, Gentamycin)

1. NAME OF THE VETERINARY MEDICINE

AMOVET-GT Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Amoxicillin as Trihydrate …….. 150 mg
Gentamicin as Sulfate...……..…….. 40 mg

Excipients:
Benzyl alcohol (E-1519) …….. 0.05 ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injectable suspension.

4. CLINICAL DATA

4.1. Target species

Bovine.

4.2. Indications for use, for each of the target species

Bovine:
Pneumonias caused by susceptible strains of *Pasteurella multocida* and *Arcanobacterium pyogenes***.

Diarrhea caused by susceptible strains of *Escherichia coli* and *Salmonella spp* **.

** Sensitive to amoxicillin and gentamicin.

4.3. Contraindications

Do not use in case of hypersensitivity to the active substance or any of the excipients.

Do not use in animals hypersensitive to penicillins. Do not use in animals with impaired kidney function.
Do not use in pregnant animals.

4.4. Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Shake the product vigorously before use. When the vial has been standing for a while, it is normal for it to separate into two layers that are easily resuspended by shaking.

When administering high doses, it is advisable to divide the medication between two or more injection sites to

promote absorption.

Good clinical practice requires that treatment be based on susceptibility testing of bacteria isolated from sick animals. If this is not possible, treatment should be based on local (regional, farm-level) epidemiological information on the susceptibility of the different strains of bacterial species commonly involved in the infectious process.

Special precautions to be taken by the person administering the medicine to animals

In case of accidental self-injection, seek medical advice and show the package leaflet or label.

People with known hypersensitivity to gentamicin and/or penicillins should avoid all contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and severity)

In very rare cases, renal dysfunction may occur during prolonged treatment with doses higher than those recommended.

Hypersensitivity reactions have occurred very rarely in sensitive animals.

The frequency of adverse reactions should be classified according to the following groups:

- Very frequently (more than 1 animal in 10 treated animals presents adverse reactions)

- Frequently (more than 1 but less than 10 animals per 100 animals treated)
- Infrequently (more than 1 but less than 10 animals per 1,000 animals treated)
- Rarely (more than 1 but less than 10 animals per 10,000 animals treated)

- Very rarely (less than 1 animal per 10,000 animals treated, including isolated cases.

4.7 Use during pregnancy, lactation or laying

The product crosses the placental barrier and may cause ototoxicity and nephrotoxicity in the fetus.

Its use is not recommended during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

It should not be used together with bacteriostatic antibiotics.

4.9 Dosage and route of administration

Intramuscular route
Cattle and Goat: 15 mg of amoxicillin trihydrate and 4,000 IU of gentamicin sulphate/kg of body weight equivalent to 1 ml of the drug/10 kg of body weight for 3 days.

4.10 Overdose (symptoms, emergency procedures, antidotes), in case of necessary

In case of poisoning due to overdose, stop the medication and administer symptomatic treatment. Administration of the medication to Goat and cattle at three times the recommended dose and for three times the recommended duration causes obvious lesions in the area of administration; in Goat, alterations related to hepatitis or nephritis may occur.

4.11 Waiting times

Bovine:
-Meat: 140 days.

Its use is not authorized in animals whose milk is used for human consumption.
Do not use in pregnant females whose milk is used for human consumption in the 2 months prior to the expected date of delivery.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combinations of antibacterials. Penicillins, combinations with other antibacterials.

ATCvet code: QJ01RA01.

5.1. Pharmacodynamic properties

Amoxicillin is a bactericidal antibiotic belonging to the penicillin group. It inhibits the synthesis of mucopeptide, one of the components of the rigid bacterial cell wall that gives mechanical stability to the bacteria, destroying the bacteria in its
growth phase.

Gentamicin is an aminoglycoside antibiotic that acts directly on the ribosome, where it inhibits protein biosynthesis and decreases the fidelity of interpretation of the genetic code.

The penetration of gentamicin into the cell is increased when the permeability of the bacterial cell wall is altered by amoxicillin. This fact allows the use of smaller amounts of the aminoglycoside.

Amoxicillin and gentamicin together have a broad antibacterial spectrum that includes Gram-positive bacteria (corynebacteria) and Gram-negative bacteria *(E. coli, Pasteurella spp, and Salmonella spp).* Their association improves the therapeutic properties of each of these antibiotics administered alone.

5.2 Pharmacokinetic data

Amoxicillin is well absorbed after parenteral administration. 17-20% of the active substance is bound to plasma proteins.
It is excreted mainly unchanged in urine and to a lesser extent in milk and bile.

Gentamicin is poorly absorbed from the gastrointestinal tract, but is well absorbed after parenteral administration. It is rapidly distributed to the kidney, liver, lung, endometrium and breast parenchyma. Its elimination occurs in a biphasic manner, with a first rapid phase corresponding to the distribution of the active substance in the tissues and a second slow phase corresponding to the release of the active substance from the tissues into the plasma and its subsequent elimination
from the plasma.

6. PHARMACEUTICAL DATA

6.1 List of excipients

Benzyl alcohol (E-1519).
Sorbitanoleate (E-494).
Medium chain triglycerides.

6.2 Main incompatibilities

In the absence of compatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

6.3 Period of validity

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Store at a temperature below 25 ºC.

6.5 Nature and composition of primary packaging

Clear, colourless Type II multidose glass vials, closed with a bromobutyl rubber stopper and aluminium flip off-seals.

Formats:
Box with 1 vial of 100 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from its use, if applicable

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER
Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORIZATION NUMBER
Reg. No.: 118398

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION
Date of Reg.: 07-09-2023

10. DATE OF TEXT REVISION
22-07-2024

MANUFACTURED BY:
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