TYLOWAN-G INJECTION

(*Tylosin, Gentamicin)*

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THSE VETERINARY MEDICINAL PRODUCT

TYLOWAN-G INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Tylosin (as Tartrate)…….100mg
Gentamicin (as Sulphate)……...50mg

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle, Goat & Sheep.

4.2 Indications for use, specifying the target species

Tylowan-G Injection is indicated in respiratory tract infections, gastrointestinal tract infections and genital tract infections like CRD, pneumonia, bronchitis, pleuritis, pasteurellosis, enteritis, gastroenteritis, salmonellosis, metritis and mastitis etc.

4.3 Contraindications

Not to be used in animals known to be hypersensitive to the active ingredient.
Combining gentamicin with tylosin increases the risk of nephrotoxicity and ototoxicity, especially in animals with pre-existing kidney problems or those receiving other potentially harmful medications.

4.4 Special Warnings for each target species

It should only be administered under close veterinary supervision with careful monitoring for signs of colitis (e.g., diarrhea, abdominal pain, lethargy).
Accurate dosing is critical to minimize the risk of toxicity. Dosages should be carefully calculated based on the animal's weight and species

4.5 Special Precautions for Use

i. Special precautions for use in animals

Not recommended for horses.

Official, national and regional antimicrobial policies should be taken into account when the product is used.

ii. Special precautions for the person administering the veterinary medicinal 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.
Tylosin may induce irritation. Macrolides, such as tylosin, may also cause hypersensitivity (allergy) following injection, inhalation, ingestion or contact with skin or eye. Hypersensitivity to tylosin may lead to cross reactions to other macrolides and vice versa.

4.6 Adverse reactions (frequency and seriousness)

Tolerance studies and toxicity studies suggest that undesirable effects are unlikely. Occasionally swelling at the injection site may occur, but this effect is transient.

Adverse effect notably kidney and ear damage (nephrotoxicity and ototoxicity), other potential issues include muscle weakness, allergic reactions, and digestive upset.

4.7 Use during pregnancy, lactation or lay

Gentamicin is contraindicated during pregnancy and lactation due to risks to the fetus/young. Tylosin's safety in these conditions varies by species; consult a veterinarian. Combining them increases risks and is typically avoided in pregnant/lactating animals. Veterinary guidance is essential

4.8 Interaction with other medicinal products and other forms of interaction

Gentamicin and Tylosin can interact with other medications, potentially increasing toxicity risks. Concurrent use of nephrotoxic or ototoxic drugs should be avoided

4.9 Amount(s) to be administered and administration route

Administer the following dose by IM:

Large Animals: 1ml per 25-30kg body weight.
Sheep / Goat: 1ml per 20kg body weight.

Administer once a day for 3-4 days.

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

Tolerance studies of up to 156% of the recommended dosage rate have been carried out with localised swelling at the injection site being the only adverse effect. The lowest recorded LD_{50} for tylosin from other acute toxicity studies was 400mg/kg bodyweight (40 times the recommended dosage rate) by intravenous injection in mice.

Gentamicin/tylosin overdose can cause kidney/ear damage, muscle weakness, and digestive upset. Seek immediate veterinary care; there are no specific antidotes.

4.11 Withdrawal period(s)

Cattle & Goat (meat & offal): 7 days.
Milk: 03 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Macrolide with Aminoglycoside Antibiotic
ATCvet code: QJ01FA90 & QJ01GB03

5.1. Pharmacodynamic properties

Tylosin is a macrolide antibiotic. It works by inhibiting bacterial protein synthesis. It binds to the 50S ribosomal subunit of susceptible bacteria, preventing the translocation of peptidyl-tRNA and thus halting protein production. This action is primarily bacteriostatic, meaning it inhibits bacterial growth rather than killing the bacteria directly.
Tylosin is mainly effective against Gram-positive bacteria and some Gram-negative bacteria, as well as Mycoplasma species. It's commonly used to treat respiratory infections, mastitis, and other infections in various animal species.

Gentamicin is an aminoglycoside antibiotic. It's a bactericidal antibiotic, meaning it kills bacteria directly. It works by interfering with bacterial protein synthesis, but through a different mechanism than tylosin. Gentamicin binds to the 30S ribosomal subunit, causing misreading of mRNA, leading to the production of non-functional proteins that disrupt bacterial cell function.
G**e**ntamicin has a broad spectrum of activity, effective against many Gram-negative bacteria and some Gram-positive bacteria.
It's often used to treat serious infections, including those caused by bacteria resistant to other antibiotics.

5.2. Pharmacokinetic properties

Tylosin tartrate is rapidly absorbed after intramuscular injection, reaching peak plasma concentrations within a few hours, though oral absorption is variable and generally lower. It distributes widely throughout the body, including lungs, liver, kidneys, and milk, and crosses the placenta. Tylosin is primarily metabolized in the liver and mainly excreted in bile, with a smaller portion eliminated in urine.

Gentamicin sulfate is well absorbed after intramuscular injection, but poorly absorbed orally, making it unsuitable for systemic infections via that route. It distributes primarily to extracellular fluids, with limited penetration of the central nervous system and placenta. Gentamicin tends to accumulate in the kidneys, is not extensively metabolized, and is primarily excreted unchanged in the urine through glomerular filtration.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf life

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

6.3 Special precautions for storage

Store below 25^{o}C
Protect from light.'
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

6.4 Nature and composition of immediate packaging

50ml amber glass vial, closed with a bromobutyl rubber stopper and capped with an aluminium flip off seal.

6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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 AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 118585

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 26-12-2023

10. DATE OF REVISION OF TEXT

20-01-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD. | 136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.