MARBOWAN INJECTION
(Marbofloxacin)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

MARBOWAN INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Marbofloxacin ……100mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Goat.

4.2. Indications for use specifying the target species

Treatment of respiratory infections caused by susceptible strains of Pasteurella multocida, Mannheimia haemolytica and Mycoplasma bovis. Treatment of acute mastitis caused by marbofloxacin-susceptible Escherichia coli strains during lactation

4.3. Contraindications

Do not use if the relevant pathogen is resistant to other fluoroquinolones (cross-resistance).
Do not use in cases of hypersensitivity to the active ingredient or any of the excipients.

4.4. Special warnings for each target species

The efficacy data showed that the product has insufficient efficacy for the treatment of acute forms of mastitis caused by Gram-positive bacteria.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Official and local antimicrobial management policies should be taken into account when using the product. Fluoroquinolones should be reserved for the treatment of clinical conditions where there has been or is expected to be an inadequate response to other classes of antimicrobials. Wherever possible, fluoroquinolones should be used only on the basis

of susceptibility testing. Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the effectiveness of therapy with other quinolones due to the potential for cross-resistance

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)

Administration by the intramuscular route may cause transient local reactions such as pain and swelling at the injection site and inflammatory lesions which may persist for at least 12 days after injection. However, in cattle, the subcutaneous route has been shown to be better tolerated locally compared to the intramuscular route. Therefore, the subcutaneous route is recommended in heavy cattle

4.7. Use during pregnancy and lactation or lay

Can be used in pregnant and lactating cows.

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

None known.

4.9. Dosage and administration route

To ensure administration of the correct dose, body weight should be ascertained as accurately as possible to avoid underdoing.
The recommended dose is 2 mg marbofloxacin/kg body weight (1 ml product/50kg body weight) in a daily injection by the intramuscular, subcutaneous or intravenous route in cattle, sheep & Goats. The neck should be preferred for injections in cattle.
Treatment may last 3 to 5 days in cattle, sheep & Goats.

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

No serious side effects are expected at doses up to 3 times or 5 times the recommended dose in cattle, Sheep and Goats respectively. When the dose is exceeded, symptoms such as neurological disorders may occur. Such symptoms should be treated symptomatically.

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

Not applicable.

4.12. Withdrawal period:

Meat and edible tissues: 6 days
Milk: 36 hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, Fluoroquinolones
ATCvet code**: QJ01MA93**

5.1. Pharmacodynamics properties

Marbofloxacin is a synthetic, broad-spectrum antimicrobial, belonging to the group of fluoroquinolone antibiotics. Marbofloxacin is a bactericide with efficacy against a broad spectrum of Gram-negative bacteria, Gram-positive bacteria and Mycoplasma species. The mechanism of action of marbofloxacin is based on the inhibition of type II topoisomerases, DNA gyrase and topoisomerase IV. A 6-year pan-European study by Kroemer, S et al 2012, reviewed the efficacy of marbofloxacin against indicated pathogens isolated from bovine respiratory diseases. In this study
751 isolates of P. multocida were identified, of which over 99% were determined to be highly susceptible to marbofloxacin with MIC ranging from 0.004 to 1 µg/ml. The MIC50 was identified as 0.015 µg/ml and the MIC90 was 0.120 µg/ml. This study also evaluated 514 isolates of M. haemolytica with > 98% of isolates determined to be highly susceptible with MIC ranges from 0.008 to 1 µg/ml, a value MIC50: 0.03 µg/ml and MIC90 value: 0.25 µg/ml. 171 isolates of M. bovis were identified with 74% showing susceptibility with MIC ranging from 0.5 to 1 µg/ml, 25% showing intermediate susceptibility with MIC: 2 µg/ ml and 1% showing resistance with MIC: 4 µg/ml. The MIC50 was 1 µg/ml and the MIC90 was 2 µg/ml; however, these were considered irrelevant due to the low number of isolates. This study also examined the efficacy of marbofloxacin in E. coli mastitis which analyzed 617 isolates and demonstrated susceptibility of over 98% with the MIC of these susceptible organisms ranging from 0.008 to 1 µg/ml. The MIC50 and MIC90 both were determined to be 0.03 µg/ml. In a pan-European study by El Garch et al., 2017, 369 E. coli isolates from porcine metritis showed 92.7% susceptibility to marbofloxacin with MIC ranging from 0.008 to 1 µg/ml. 0.3% of the isolates showed intermediate susceptibility with MIC 2 and 7% showed resistance with MIC> 4. The MIC50 was determined to be 0.03 µg/ml and the MIC90 was 0.5 µg/ml. The pan-European studies by Kroemer, S et al 2012 and El Garch, F. et al., 2017, established clinical susceptibility breakpoints for marbofloxacin in bovine respiratory disease associated with P. multocida and M. Haemolytica and in bovine mastitis and metritis associated with E. coli. Resistant strains identified had MIC ÿ 4 µg/ml, intermediate strains had MIC=2 µg/ml and susceptible strains had MIC 1 µg/ml. Clinical susceptibility breakpoints have not been established for Mycoplasma species. Resistance to fluoroquinolones is mainly due to chromosomal mutations through three mechanisms: reduction of bacterial wall permeability, expression of the efflux pump or mutations in the enzymes responsible for binding the molecules. Plasmid resistance to quinolones is a different mechanism by which resistance can develop. This can occur through three different mechanisms: through plasmid genes encoding proteins that protect DNA gyrase and topoisomerase IV from quinolone inhibition, through acetylation of some quinolones by a variant of the acetyltransferase AAC (6')-Ib or through plasmid genes encoding enhanced efflux pumps. While the low-level resistance this confers does not exceed clinical susceptibility limits, it may allow selection of higher-level resistances.

5.2 Pharmacokinetic information

After subcutaneous or intramuscular administration to cattle and administration to pigs at the recommended dose of 2 mg/kg body weight, marbofloxacin is rapidly absorbed and reaches a maximum blood plasma value of 1.5 µg/ml within 1 hour. The bioavailability of marbofloxacin is close to 100%. Marbofloxacin is poorly bound to plasma proteins (less than 10% in pigs and 30% in cattle), is widely distributed and reaches a higher concentration in most tissues (liver, kidneys, skin, lungs, bladder, uterus and digestive tract) than in blood plasma. In cattle, marbofloxacin is eliminated slowly in pre-ruminant calves, but more rapidly in ruminant cattle (t1/2 = 5 9 hours and 4 – 7 hours respectively). In the case of calves in the pre-ruminant phase, the elimination of the active form occurs mainly through the urine, (¾ urine, ¼ feces). In ruminant cattle, the active form is eliminated equally in the urine and feces.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipient

Monothioglycerol
Metacresol
Disodium Edetate
Gluconolactone
Water for injections

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 first opening the container: use within 28 days, do not store.

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

Cardboard box with glass injection vial.
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 50ml

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.: 088847

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 06-04-2018

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

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