

NAWAJECT INTRAMAMMARY SUSPENSION

*(Cloxacillin Benzathine, Neomycin Sulphate,
Prednisolone Sulphate)*

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NAWAJECT INTRAMAMMARY SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4gm Contains:

Cloxacillin Benzathine 300mg

Neomycin Sulphate 200mg

Prednisolone Sulphate 10mg

3. PHARMACEUTICAL FORM

Intramammary Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Goat.

4.2. Indications for use specifying the target species

Breast infections caused by germs sensitive to cloxacillin and neomycin.

In cows at dry-off:

- Treatment of subclinical mastitis caused by *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* and *Streptococcus uberis*
- Prevention of new infections during the dry period.

4.3. Contraindications

Do not use in cases of hypersensitivity to any of the excipients. Do not use if you have a history of allergy to penicillins and/or aminoglycosides

4.4. Special warnings for each target species

Do not milk after administering the veterinary medicinal product.

4.5. Special precautions for use

Special precautions for safe use in the target species:

After the last milking, disinfect the teat opening and administer through the teat canal, respecting the usual aseptic precautions, the entire contents of an intramammary Tube into each quarter. It is recommended to then proceed with a final dip of the teats with an appropriate disinfectant solution

The efficacy of the veterinary medicinal product has only been established against the germs mentioned in the indications (section "Indications for use for each target species"). Consequently, the occurrence after drying off of severe mastitis (which may be fatal) due to other germs, in particular *Pseudomonas aeruginosa*, remains possible.

To reduce this risk, the rules of asepsis during the administration of the veterinary medicinal product must be scrupulously respected; monitoring of the cows in the days following drying off and their maintenance in a hygienic environment far from the milking environment must also be ensured.

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

Penicillin's may cause hypersensitivity reactions after injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin's may result in cross-allergy with aminoglycosides and vice versa. These hypersensitivity reactions may occasionally be serious

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)

Allergic reactions¹, agitation, tremor, swelling of the mammary gland, eyelids and lips

Frequency not known (cannot be estimated from the available data)

Reporting of adverse events is important. It allows the continuous monitoring of the safety of the veterinary medicinal product. Reports should be sent, preferably by the veterinarian, either to the marketing authorization holder or his local representative, or to the national competent authority via the national reporting system. Please refer to the package leaflet for the respective contact details.

4.7. Use during pregnancy and lactation or lay

Can be safely administered to pregnant or lactating animals

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

None known.

4.9. Dosage and administration route

Intramammary route.

Cloxacillin Benzathine 300mg, Neomycin Sulphate 200mg, Prednisolone Sulphate 10mg or the contents of one tube per quarter at drying off, immediately after the last milking

During the last milking before the dry period, milk all four quarters of the udder completely

Clean and disinfect the teats, then inject the entire contents of an intramammary Tube per quarter. Do not milk again after that

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

None known.

4.11. Special restrictions on use and special conditions of use, including restrictions on the use of antimicrobial and anti-parasitic veterinary medicinal products, in order to limit the risk of development of resistance

Not applicable.

4.12. Withdrawal period:

Milk for human consumption must not be taken from a cow during treatment. With cows milked twice daily, milk for human consumption may only be taken from 96 hours (i.e. at the 8th milking) from the last treatment. Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 4 days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combinations of antibacterial for intramammary use; Antibacterial and Corticosteroids. ATCvet Code: **QJ51RV01**

5.1. Pharmacodynamics properties

Neomycin is an aminoglycoside antibiotic that binds to the 30S ribosomal subunit, inhibiting bacterial protein synthesis. It is primarily effective against Gram-negative bacteria (e.g., *E. coli*, *Klebsiella*). It has limited activity against Gram-positive bacteria and anaerobes.

Cloxacillin is a penicillinase-resistant penicillin. It inhibits bacterial cell wall synthesis by binding to PBPs. It is particularly effective against beta-lactamase-producing *Staphylococcus aureus*.

Prednisolone acetate, a synthetic corticosteroid, exerts its anti-inflammatory and immunosuppressant effects by binding to intracellular glucocorticoid receptors. This interaction modulates gene transcription, leading to the synthesis of proteins that inhibit inflammation (e.g., lipocortin) and suppress the immune system. It also affects carbohydrate, protein, and fat metabolism.

5.2 Pharmacokinetic information

Neomycin poorly absorbed from the gastrointestinal tract when administered orally; primarily acts locally in the gut, absorbed neomycin is excreted renally, Systemic absorption can lead to nephrotoxicity and ototoxicity, especially in animals with renal impairment Cloxacillin Well-absorbed orally in animals, Distributed widely, including to bones and joints, Metabolized in the liver and excreted primarily in the urine, Benzathine salt provides a prolonged release, extending the duration of action.

Prednisolone acetate is a prodrug that is rapidly hydrolyzed to its active form, prednisolone, after administration. Prednisolone is highly protein-bound in the plasma. It is primarily metabolized in the liver and the resulting metabolites are excreted mainly in the urine.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Aluminium monostearate
Veseline
Liquid paraffin

6.2 Incompatibilities

Do not mix with other veterinary medicinal products

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store below 25°C.
Protect from direct sunlight.
Store in a tightly closed tube.
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

4gm Polyethylene Intramammary Tube.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

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.: 022717

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 11-02-1999

10. DATE OF REVISION OF THE TEXT

17-02-2025