Nefa-Mac IMM Injector

نیفا-میک ۱۰ ملی لیٹر
آئی ایم ایم انجیکٹر

Cephalexin Monohydrate,
Neomycin Sulphate,
Cloxacillin Benzathine & Vitamin A)

Intramammary suspension
Antibiotic infusion for dry cows

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Nefa Mac IMM Injector, intramammary suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
1 mL contains:
Cephalexin Monohydrate ..... 200 mg
Neomycin Sulphate ..... 340 mg
Cloxacillin Benzathine ..... 500 mg
Vitamin A ..... 10,000 IU
(As per Innovator's Specification)

3. TARGET SPECIES

3.1. Target Animal Species
Cattle (dairy cows).

3.2. Indications for Use, Specifying the Target Animal Species
Nefa Mac IMM Injector is indicated for the treatment of clinical and subclinical mastitis in dairy cows caused by cephalexin, neomycin, and cloxacillin-sensitive organisms, including:
- Staphylococcus aureus
- Streptococcus agalactiae
- Escherichia coli
- Corynebacterium spp.

The inclusion of Vitamin A supports udder tissue repair and overall health during and after the infection.

3.3. CONTRAINDICATIONS
- Do not use in animals with known hypersensitivity to cephalexin, neomycin, cloxacillin, or any other beta-lactam antibiotics.
- Not to be used in cows with severe renal or hepatic impairment.

3.4. Special Warnings for Specific Target Animal Species
None.

3.5. Special Precautions for Use
Special precautions for use in animals:
- Nefa Mac IMM Injector should be used in cases where mastitis has been diagnosed, and susceptibility testing has confirmed the effectiveness of the active ingredients.
- Use of the product should be based on a susceptibility test where possible. The improper use of antimicrobials may contribute to an increase in resistant bacteria.
- Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- Penicillin and cephalosporins can cause allergic reactions. Avoid contact with skin, eyes, and mucous membranes.
- If allergic reactions occur, such as skin rash, seek medical advice immediately and show this leaflet to the doctor.
- In case of accidental self-injection, seek medical advice immediately.

3.6. ADVERSE REACTIONS (FREQUENCY AND SEVERITY)
- Possible local reactions at the injection site, including swelling or redness.
- Allergic reactions may occur in some animals. If signs of an allergic reaction appear, discontinue use and seek veterinary advice.

3.7. USE DURING PREGNANCY, LACTATION, OR EGG LAYING
- Nefa Mac IMM Injector is intended for use during lactation. However, ensure the withdrawal period is observed before milk is used for human consumption.

3.8. Interactions with Other Drugs and Other Forms of Interaction
- Avoid concurrent use with other intramammary treatments unless prescribed by a veterinarian.
- Do not use with other aminoglycosides, beta-lactam antibiotics, or nephrotoxic drugs.

3.9. DOSAGE AND METHOD OF ADMINISTRATION
- Administer one syringe (1 mL) into each affected quarter of the udder.
- Before administration, milk out the affected quarter completely and clean and disinfect the teat end.
- Insert the syringe tip into the teat canal and inject the entire content. After administration, gently massage the udder to distribute the product.
- Note: The treatment should be repeated every 12 hours for 3 consecutive milking or as directed by a veterinarian.

3.10. Overdose (Symptoms, Emergency Procedures, Antidotes), If Necessary
- Overdose is unlikely when administered as directed. If overdose occurs, symptomatic treatment should be provided. Monitor renal function due to the presence of neomycin.

3.11. Withdrawal Period
- Meat and offal: 28 days.
- Milk:96 hours after the last treatment.

4. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group:
Intramammary antibacterial agents with Vitamin A.

Pharmacodynamics:
CEPHALEXIN:
Pharmacodynamics and Benefits of Nefa Mac IMM Injector in the Udder

Cephalexin Monohydrate:
Cephalexin is a first-generation cephalosporin antibiotic that effectively targets Gram-positive bacteria, particularly *Staphylococcus spp.* and *Streptococcus spp.* It works by inhibiting bacterial cell wall synthesis, leading to cell lysis and death. Cephalexin is particularly beneficial for treating mastitis caused by susceptible bacteria in the udder. Its strong bactericidal action ensures rapid clearance of infection, reducing inflammation, and promoting the restoration of normal milk production.

Neomycin Sulphate:
Neomycin is an aminoglycoside antibiotic with potent activity against Gram-negative bacteria such as *Escherichia coli*. It binds to the 30S ribosomal subunit, disrupting protein synthesis and causing bacterial cell death. Neomycin is crucial for treating mastitis involving Gram-negative pathogens, which are common in mixed bacterial infections. Its inclusion ensures broad-spectrum coverage, leading to a more comprehensive treatment of udder infections and preventing recurrence.

Cloxacillin Benzathine:
Cloxacillin is a penicillinase-resistant beta-lactam antibiotic that is highly effective against penicillin-resistant staphylococci, including *Staphylococcus aureus*.
It inhibits bacterial cell wall synthesis, similar to other beta-lactams.
Cloxacillin provides targeted action against penicillin-resistant strains, which are a common cause of persistent or recurrent mastitis. The benzathine form allows for sustained release, ensuring prolonged antibiotic activity in the udder, thus enhancing treatment efficacy and reducing the risk of chronic infection.

Vitamin A:
Vitamin A is essential for maintaining the integrity of epithelial tissues and supporting immune function. It plays a vital role in cellular differentiation, immune response, and tissue repair.
In the context of mastitis, Vitamin A aids in the repair and regeneration of damaged udder tissue. It promotes faster healing, reduces the risk of chronic lesions, and enhances the overall health of the mammary gland. This not only speeds up recovery but also helps in preventing future infections, ensuring sustained milk production.

Pharmacokinetics:
The active ingredients are absorbed from the mammary gland after intramammary administration, achieving effective concentrations in the udder tissue. They are metabolized primarily in the liver and excreted in urine and milk.

5. PHARMACEUTICAL DATA

5.1. Major Incompatibilities
- Do not mix with any other veterinary medicinal product.

5.2. Shelf Life
- 2 years when stored under recommended conditions.
- Use immediately after opening the syringe.

5.3. Special Storage Precautions
- Store below 25°C in a dry place.
- Protect from light. Do not freeze.
- Keep out of reach of children.

5.4. How to Supplied
- 10 mL single-use syringes, packed in cartons containing 12 syringes.

5.5. Special Precautions for Disposal of Unused Veterinary Medicinal Product or Waste Material Derived from the Use of Such Products
- Any unused veterinary medicinal product or waste material should be disposed of in accordance with local requirements.

MANUFACTURED BY:
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