NOWADRY INTRAMAMMARY SUSPENSION

(Penicillin G Procaine & Novobiocin Sodium)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NOWADRY INTRAMAMMARY SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10ml Contains:
Penicillin G Procaine …….. 200,000 IU
Novobiocin Sodium ……..……..400mg

3. PHARMACEUTICAL FORM

Intramammary Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Cattle (Dry Cow).

4.2. Indications for use specifying the target species

For the treatment of mastitis in cows during the dry period, when the causative agents of mastitis are Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae and Streptococcus uberis. An aid for the control of summer mastitis, which occurs in cows that are in heat during the summer.

4.3. Contraindications

Known hypersensitivity to the active substances or to any of the excipients.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:

None.

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

Avoid contact of this veterinary medicinal product with the skin.
Penicillin's and cephalosporin's can cause hypersensitivity (allergy) after contact. Hypersensitivity to penicillin can cause cross-reactions to cephalosporin's and vice versa.
Allergic reactions to these substances can sometimes be serious.
Avoid contact with this veterinary medicinal product if you are hypersensitive to it or have been advised not to work with any of its ingredients.
All recommended precautions should be followed when using this veterinary medicinal product.
If a skin rash occurs after using this veterinary medicinal product, seek medical advice immediately. If serious symptoms occur such as swelling of the face, lips and eyes or difficulty breathing, seek medical advice immediately.

4.6. Adverse reactions (frequency and seriousness)

None.

4.7. Use during pregnancy and lactation or lay

Pregnancy: Can be used during pregnancy.
Lactation: Do not use during lactation.

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

Not known.

4.9. Dosage and administration route

Administer by infusion into the udder after the last milking before solidification. The solidification period should be planned to be longer than 30 days. Before use, Nowadry should be shaken thoroughly, the teats cleaned and disinfected, and the entire contents of the syringe infused into each quarter of the udder.

In cows with an expected dry period of more than 51 days, treatment may be repeated after an interval of 3 weeks. It is recommended to re-treat each teat with a suitable teat disinfectant after infusion.

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

Before milk is used for human consumption, it must be tested for antibiotic residues.

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:

If the cow's dry period is 30 days or longer, milk may be used for human consumption 84 hours after calving.
If the cow's dry period is up to 30 days, the milk should be tested for the presence of antibiotics or it can be used for human consumption after 30 days + 3 days after the last infusion.

During treatment, it is prohibited to slaughter animals whose meat is intended for human consumption.
If the meat of the animals is intended for human consumption, the animals may only be slaughtered 30 days after the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antimicrobials
ATCvet code. **QJ51RC23**

5.1. Pharmacodynamics properties

Nowadry contains the active ingredients procaine benzylpenicillin and novobiocin in an oil-based formulation, which provides a long-lasting effect. Penicillin has bactericidal activity by inhibiting cell wall synthesis, which leads to the death of bacterial cells. Novobiocin has bacteriostatic and bactericidal activity by inhibiting bacterial cell division, specifically by inhibiting DNA gyrase. Penicillin provides antibacterial activity against streptococci (Streptococcus dysgalactiae, Streptococcus agalactiae, and Streptococcus uberis) and beta-lactamase-non-producing Staphylococcus aureus, and novobiocin acts on beta-lactamase-producing (and beta-lactamase-non-producing) S. aureus. The combination has been shown to be synergistic against S. aureus both in vitro and in vivo.

5.2. Pharmacokinetic information

Concentrations exceeding the minimum inhibitory concentration (MIC) against target pathogenic bacteria are achieved within 24 hours of treatment, with therapeutic levels maintained for up to 3-4 weeks.

6. PHARMACEUTICAL INFORMATION

6.1. List of Excipients

Aluminum monostearate
Peanut oil

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.

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

10ml 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.: 091888

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 19-09-2018

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.