AMPICOX INJECTION
(Ampicillin Trihydrate & Cloxacillin Base)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AMPICOX INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Ampicillin (as Trihydrate) ….. 12.5gm
Cloxacillin Base …… 12.5gm

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL INFORMATION

4.1. Target species

Horses, Cattle, Dogs & Cats.

4.2. Indications for use specifying the target species

For the treatment of respiratory, gastrointestinal and urogenital infections, sepsis and skin infections caused by Gram-positive and Gram-negative microorganisms, sensitive to ampicillin and cloxacillin.

4.3. Contraindications

Do not use in case of hypersensitivity to the active ingredients or any of the excipients.

4.4. Special warnings for each target species

Not Reported

4.5. Special precautions for use

Special precautions for safe use in the target species:

The use of the product should be based on susceptibility testing of bacteria isolated from animals.
If this is not possible, treatment should be based on local epidemiological data (area, farm). Use of the product deviating from the instructions given may increase the frequency of bacteria that are resistant and may decrease the effectiveness of treatment with other antimicrobials due to possible cross-resistance.

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

People with known hypersensitivity to the active substances or to any of the excipients should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6. Adverse reactions (frequency and seriousness)

Allergic reactions are possible but are self-limiting. In such cases, administration should be discontinued and appropriate treatment should be administered, as advised by a veterinarian.

The frequency of adverse reactions is defined using the following convention:- very common (more than 1 in 10 animals displaying adverse reaction(s) during treatment) - common (more than 1 but less than 10 animals in 100 animals treated) - uncommon (more than 1 but less than 10 animals in 1,000 animals treated) - rare (more than 1 but less than 10 animals in 10,000 animals treated) - very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7. Use during pregnancy and lactation or lay

It can be used during pregnancy and lactation.

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

Semisynthetic penicillins can be combined with aminoglycoside antibiotics. The product should not be administered concurrently with bacteriostatic antibiotics.

4.9. Dosage and administration route

SHAKE WELL BEFORE USE.

This Product injectable suspension should be administered to the various target animal species deeply intramuscularly, once daily, for 3 days, at the following dosages:

Cattle, horses: 4-8 ml per 100 kg body weight (equivalent to 5-10 mg ampicillin + 2.5-5 mg cloxacillin/kg b.w.)

dogs and cats: 0.4 - 1.2 ml per 10 kg body weight (equivalent to 5-15 mg ampicillin + 2.5-7.5 mg cloxacillin/kg s.b.). Generally, higher dosages are recommended for treating infections caused by Gram-negative bacteria.

To ensure correct dosing, body weight should be determined as accurately as possible to avoid underdosing.

The dosage may be doubled, at the discretion of the veterinarian

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

There is no information regarding acute overdose.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

Cattle Meat and offal: 4 days Milk: 48 hours
Not Applicable for: Horses, Dogs & Cats

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, ampicillin, combination
ATCVet Code: **QA05BA**

5.1. Pharmacodynamics properties

Ampicillin is an antibiotic of the β-lactam group. It has a broad antimicrobial spectrum against both Gram-positive and Gram-negative microorganisms. Cloxacillin is a semi-synthetic penicillin and is active against Gram-positive microorganisms, especially against staphylococci that produce penicillinase. Both penicillins have bactericidal action and interfere with the formation of the bacterial cell, causing its lysis. The combination of the two penicillins allows for synergy to be achieved.
The action of ampicillin is enhanced through the inactivation caused by cloxacillin of penicillinase. This synergy, demonstrated in vivo and in vitro, is achieved due to the reduction of the 'Minimum Inhibitory Concentration' (MIC) of each active ingredient, and due to the increase in their non-protein-bound percentage in the blood and various organic fluids.

5.2. Pharmacokinetic information

After parenteral administration, both penicillins are rapidly absorbed and distributed to various organs and tissues. Excretion occurs in their original form mainly via urine and partially via bile.

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients

Polyoxyethylated glycerides
Fractionated coconut 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.
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.
Shake well before use.
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 (s).
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 50ml Vial & 100ml Vial

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.: 035061

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 13-12-2004

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:
NAWAN LABORATORIES (PVT) LTD.
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