Nawacin-50 Injection
(Oxytetracycline)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nawacin-50 Injection 50mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Oxytetracycline (as hydrochloride)…….. 5g

3. CLINICAL PARTICULAR

3.1 Animal species for which the veterinary medicinal product is intended

Cattle, sheep, goats, dogs and cats.

3.2 Therapeutic indications specifying the target species

Cattle: actinobacillosis, shot, pneumonia, pasteurellosis, mastitis, metritis, colibacillosis.

Sheep and goats: puerperal infections, mastitis, pneumonia.
Dogs and cats: respiratory, urogenital and gastrointestinal infections, septicemia.

3.3 Contraindications

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

3.4 Special precautions for use in each target species

Do not administer intravenously to dogs and cats.

3.5 Special precautions for use

Special precautions for animals when using the product

Intravenously it should be administered very slowly.
When administering NAWACIN-50 INJECTION. 5% intramuscularly, do not inject more than 20 ml in cattle and 6 ml in sheep and goats at one site.

Special precautions to be taken by the person administering the veterinary medicinal product to animals the animals

Not applicable.

3.6 Adverse reactions (frequency and seriousness)

The use of tetracyclines during tooth development may cause discoloration of the teeth. Intramuscular administration may cause painful swelling at the injection site, which is transient and resolves quickly.

3.7 Use during pregnancy, lactation or lay

The use of tetracyclines during tooth development, including in advanced pregnancy, may lead to a change in tooth color.

3.8 Interaction with other veterinary medicinal products and other forms of interaction

Tetracyclines bind and precipitate as insoluble yellow salts on ossifying tissues - bones and teeth, causing a change in their color.

3.9 Dosage and administration

Parenteral administration: deep intramuscular or intravenous injection.
Oxytetracycline is administered in doses of 5 – 10 mg/kg body weight.
This corresponds to 1 – 2 ml per 10 kg body weight daily. In acute cases, it is advisable to start treatment with intravenous administration of 2 ml 10 kg body weight followed by intramuscular administration of 1 ml / 10 kg body weight daily.

3.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No information available.

3.11 Withdrawal periods

Meat and offal: 22 days. Milk: 7 days.

4. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: anti-infectives for systemic use, Anatomical Therapeutic Code: QJ01AA06

4.1 Pharmacodynamic properties

Tetracyclines act by inhibiting protein synthesis in susceptible microorganisms. Tetracyclines enter the cell cytoplasm, penetrating the outer cell membrane by diffusion, and through the inner cell membrane by active transport. Once in the cytoplasm, tetracyclines bind irreversibly to receptors on the bacterial 30S ribosomal subunit, which prevents the binding of aminoacyl-transfer RNA to the acceptor site of the messenger RNA-ribosomal complex. This binding effectively prevents the addition of amino acids to the nascent peptide chain, inhibiting bacterial protein synthesis.

Oxytetracycline is a broad-spectrum antimicrobial agent, effective against Gram-positive and Gram-negative microorganisms, mycoplasmas, chlamydia, rickettsia and protozoa.
The most sensitive bacteria to tetracyclines are: beta-hemolytic Streptococci, non-hemolytic Streptococci, Clostridia, Brucella, Haemophilus Klebsiella.

4.2 Pharmacokinetic properties

After absorption, tetracyclines enter the bloodstream, where they bind to blood proteins. After intramuscular administration, maximum blood concentrations are reached after 2 hours. Oxytetracycline readily passes into milk. Therefore, therapeutic levels in milk can be reached after a single intravenous administration.

Most tetracyclines are excreted via the renal glomeruli as parent substances or their metabolites. Small amounts are excreted via the gastrointestinal tract, through the bile.

5. PHARMACEUTICAL PARTICULARS

5.1 Shelf life

Shelf life of the finished veterinary medicinal product: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.2. Special storage conditions for the product

Store below 25°C. Store in a dry place. Protect from heat, light. Keep out of reach of children

5.3 Nature and composition of immediate packaging

Glass vial with bromobutyl rubber stopper and aluminium flip off seal.

5.4 Special precautions for the disposal of unused product or waste materials derived from it

Any unused veterinary medicinal product or waste material should be disposed of in accordance with local requirements.

6. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

7. MARKETING AUTHORISATION NUMBER

Reg. No.: 023417

8. DATE OF FIRST AUTHORISATION

Date of Reg.: 17-05-1999

9. DATE OF REVISION OF THE TEXT

05-06-2024