TRIMODIN-48 INJECTION

(Trimethoprim, Sulphadiazine)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

TRIMODIN-48 INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Trimethoprim ……..…… 8gm
Sulphadiazine ……..... 40gm

3. PHARMACEUTICAL FORM

Suspension for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep & Horses

4.2. Indications for use specifying the target species

It is recommended for horses, cattle, and sheep in the treatment of infections caused by organisms sensitive to the action of the active substances:
- Bacterial infections of the respiratory system: pneumonia, bronchitis, rhinitis and in secondary infections following viral pneumonia or mycoplasma infection.
- Digestive tract infections: neonatal diarrhea and salmonellosis. It can be administered in the treatment of other conditions: pododermatitis, mastitis, conjunctivitis, otitis, and stomatitis.

4.3. Contraindications

Do not administer intravenously or intraperitoneally.
Do not administer to animals with known hypersensitivity to the active substances or to any of the excipients

4.4. Special warnings for each target species

Not Specified.

4.5. Special precautions for use

Special precautions for use in animals:

The use of the product should be based on susceptibility testing of bacteria isolated from animals. Official, national and regional antimicrobial policies should be followed when using the product. If this is not possible, therapy should be based on epidemiological information on the susceptibility of bacteria isolated from animals.

Use of the product deviating from the instructions in the SPC may lead to an increase in the prevalence of resistance to the active substances and may reduce the effectiveness of treatments with tetracycline antimicrobials due to cross-resistance

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

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)

A swelling (tumefaction) may rarely occur at the injection site, which disappears quickly.

4.7. Use during pregnancy and lactation or lay

Can be used during pregnancy and lactation.

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

Do not administer simultaneously with procaine penicillin and products containing calcium ions. When administered simultaneously with antioxidants, the bioavailability of the product is reduced.
Sulfonamides may increase the activity of furosemide, thiazide diuretics, carbonic anhydrase inhibitors and sulfonylureas.

4.9. Dosage and administration route

The product is administered intramuscularly.

The dose is 15-20 mg sulfadiazine trimethoprim/kg body weight, equivalent to 1 ml TRIMODIN-48 Injection / 30 kg body weight or 1 ml TRIMODIN-48 Injection /25 kg body weight, depending on the severity of the diagnosis. Usually a single dose is effective.
In severe cases, treatment should be continued with daily administration of the product for up to 2 days after the disappearance of symptoms but not more than five days.
To ensure correct dosing and to avoid under dosing, the body weight of the animals should be determined as accurately as possible

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

No data available.

4.11. Withdrawal period:

Cattle & sheep:
Meat and offal: 28 days.
Milk: 3 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for Systemic Use, Combinations of Sulfonamides and Trimethoprim
ATCvet code: **QJ0IEW10**

5.1. Pharmacodynamics properties

Sulfadiazine belongs to the group of sulfonamides, a group of synthetic substances with a broad antimicrobial spectrum that are antagonists of x-aminobenzoic acid, resulting in inhibition of the biotransformation of folic acid, which is necessary for the growth and multiplication of sensitive bacteria.

Trimethoprim belongs to the diaminopyrimidines, a group of synthetic substances with a broad antimicrobial spectrum that inhibit the transformation of dihydrofolic acid into tetrahydrofolic acid, which is necessary for the biosynthesis of purines, of the amino thiaminic acid and in the synthesis of DNA in sensitive bacteria.

The active substances are effective against a broad spectrum of Gram-positive and Gram-negative bacteria, including the following: Escherichia spp. Salmonella spp., Pasteurella spp. Streptococcus spp., Staphylococcus spp., Corynebacterium spp. Clostridium spp. Erysipelothrix rhusiopathiae, Nocardia asteroides, Klebsiella pneumoniae, Shigella spp. Vibrio comma, Haemophilus spp., Bordetella spp., Proteus spp., Bacillus anthracis, Mycobacterium tuberculosis and Pseudomonas aeruginosa.

The combination of sulfadiazine-trimethoprim exhibits synergistic activity (amplified synergy), produces a double blockade in the folic acid synthesis sequence, thus the level of activity is several times higher than that obtained by each substance separately.

5.2 Pharmacokinetic information

The combination of sulfadiazine-trimethoprim is evenly distributed throughout the body. Both active substances cross the placenta and are distributed in milk.
The combination of sulfadiazine-trimethoprim is excreted unchanged by glomerular filtration and tubular secretion and metabolized in the liver.
Sulfonamides are initially acetylated and conjugated with glucuronic acid, and trimethoprim is metabolized to oxides and hydroxylated metabolites.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product should not be administered concomitantly with other veterinary medicinal products.

6.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use immediately within 28 days do not store.

6.2. Special precautions for storage

Store below 30°C.
Protect from light.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.3. Nature and composition of primary conditioning

Amber type II glass vials, closed with a nitrile rubber stopper and sealed with an aluminium cap of 10 ml and 50 ml.

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.: 020801

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 20-01-1998

10. DATE OF REVISION OF THE TEXT

05-01-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.

136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.