DIMADIN INJECTION
(Sulphadimidine)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

DIMADIN INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Sulphadimidine ……..33.333gm

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Goat, Poultry & Rabbit.

4.2. Indications for use specifying the target species

In cattle, sheep and goats:
- Treatment and metaphylaxis of respiratory and digestive infections.

In poultry and rabbits:
- Treatment and metaphylaxis of respiratory and digestive infections.
- Treatment and metaphylaxis of digestive coccidiosis.

The presence of the disease in the group must be established before use of the product.

4.3. Contraindications

Do not use if you have a history of sulfonamide allergy
Do not use in animals with severe renal or hepatic impairment.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for safe use in the target species:
Use of the product should be based on culture and sensitivity of microorganisms collected from diseased animals on the farm or from previous recent experience on the farm. Use of the product deviating from the recommendations of the SPC may increase the prevalence of sulfadimidine-resistant bacteria and may also decrease the effectiveness of other sulfonamides due to the possibility of cross-resistance.

Official and local policies regarding antibiotic therapy should be taken into consideration when using the product.

Water treated animals thoroughly, during and after treatment.

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

Handle this product with the recommended precautions to avoid any risk of exposure: wearing protective goggles and gloves is recommended when preparing the solution Avoid contact with skin and eyes.

If symptoms such as a rash develop after exposure to the product, consult a doctor and show this warning. Swelling of the face, lips or eyelids or difficulty breathing are more serious symptoms and require urgent medical attention.

Avoid handling this product if you have a history of sulfonamide allergy.

4.6. Adverse reactions (frequency and seriousness)

The potential adverse effects of sulfonamides are numerous, but in veterinary practice they are rarely observed. Possible hypersensitivity reactions.

Crystalluria with hematuria if the amount of water consumed is insufficient. Digestive disorders linked to a disruption of the digestive flora. Other side effects are possible after prolonged treatment: photosensitization, dry keratoconjunctivitis, bone marrow depression (aplasia, granulocytopenia, and thrombocytopenia), hepatitis, jaundice.

4.7. Use during pregnancy and lactation or lay

No teratogenic effects have been observed with sulfadimidine in laboratory animals (mice, rats and rabbits). The safety of the product has not been evaluated in the target species. The use of the drug will depend on the benefit/risk assessment carried out by the veterinarian.

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

None known.

4.9. Dosage and administration route
Intravenous, intramuscular or intraperitoneal routes.

In cattle, sheep, goats:
90 mg of sulfadimidine per kg of body weight per day for 3 consecutive days, by intravenous, intramuscular or intraperitoneal route, i.e. 3 mL per 10 kg of body weight per day for 3 consecutive days.

In poultry and rabbits:
150 mg to 180 mg of sulfadimidine per kg of body weight per day for 3 consecutive days,

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

Not known.

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, sheep and goats:
Meat and offal: 12 days.
Milk: 5 days.

Rabbits:
Meat and offal: 12 days.

Poultry:
Meat and offal: 12 days.
Eggs: In the absence of an MRL for eggs, do not use in laying species producing eggs for consumption, 4 weeks before the start of laying and during laying.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: systemic anti-infective, sulfonamides.
ATCVet Code: **QJ01EQ03.**

5.1. Pharmacodynamics properties

Sulfadimidine is a short-acting, broad-spectrum sulfonamide that also exhibits anticoccidial properties. It is active against Gram-positive and Gram-negative bacteria and some protozoa such as coccidia. It inhibits bacterial multiplication by acting as a competitive inhibitor of the incorporation of para-aminobenzoic acid into the folic acid metabolism cycle.

5.2. Pharmacokinetic information

Sulfadimidine is widely distributed throughout the body. It is metabolized primarily by the liver to acetylated and glucuronide conjugates, both of which are inactive. Elimination is primarily renal by glomerular filtration, with minimal tubular secretion or reabsorption.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

The drug may precipitate upon contact with solutions containing calcium.

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 in 28 days, do not store.

6.2. Special precautions for storage

Store below 25°C.
Protect from light and moisture.
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 colour glass vial with bromobutyl rubber stopper and aluminium flip of seal.
Pack size: 100 ml & 400ml

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.: 025384

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 09-05-2000

10. DATE OF REVISION OF THE TEXT

17-02-2025