

# **NAWAZAN SUSPENSION**

## ***(Levamisole HCl & Oxyclozanide)***

### **SUMMARY OF PRODUCT CHARACTERISTICS**

#### **1 NAME OF THE VETERINARY MEDICINAL PRODUCT**

NAWAZAN SUPENSION

#### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 100ml Contains:

Levamisole HCl .....1.5gm

Oxyclozanide .....3.0gm

#### **3. PHARMACEUTICAL FORM**

Oral Suspension.

#### **4. CLINICAL INFORMATION**

##### **4.1. Target species**

Sheep & Cattle.

##### **4.2. Indications for use specifying the target species**

Nawazan Suspension is indicated for the treatment and control of gastrointestinal and pulmonary nematode infections in cattle and sheep. It is also effective in the treatment of parasitic gastroenteritis and lungworm infestations caused by organisms sensitive to Levamisole hydrochloride and Oxyclozanide.

##### **4.3. Contraindications**

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

##### **4.4. Special warnings for each target species**

Care should be taken when treating heavily pregnant animals or animals under stress from Adverse weather conditions, poor nutrition, penning, handling etc. The veterinary medicinal product is not effective against Type II Ostertagiasis (winter scours) in cattle. In cases of lungworm infections, coughing may persist for a considerable time following successful treatment with the veterinary medicinal product. This is due to tissue damage caused by the parasites.

Care should be taken to avoid the following practices because they increase the risk of Development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintic from the same class, over an extended period of time.

- Under dosing which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Fecal Egg Count Reduction Test). Where the results of the tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to

another pharmacological class and having a different mode of action should be used.

#### 4.5. Special precautions for use

##### Special precautions for use in animals:

When using a dosing gun to administer this product, care must be taken to avoid dosing gun pharyngitis. After treatment, animals should be moved to clean pasture in order to prevent reinfection. Where this is not done, further dosing at 10-14 day intervals may be necessary.

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

When using, do not eat, drink or smoke.

Wash splashes from eyes and skin immediately.

Take off immediately any contaminated clothing.

Wash hands and exposed skin before meals and after work.

Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

#### 4.6. Adverse reactions (frequency and seriousness)

Species: Cattle

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea <sup>1</sup> Increased bowel movements (frequency) <sup>1</sup> Inappetence <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Photosensitisation <sup>2</sup> Skin inflammation <sup>2</sup> Skin slough <sup>3</sup>

<sup>1</sup> Transient.

<sup>2</sup> Particularly non pigmented skin e.g., muzzle, udder and which may be painful.

<sup>3</sup>In severe cases of photosensitization.

Species: Sheep

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic-type reaction <sup>1</sup> Swelling <sup>1</sup>
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<sup>1</sup> Of the head.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorization holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

#### 4.7. Use during pregnancy and lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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

Concurrent treatment with products containing organophosphorus compounds or Diethylcarbamazine citrate should be avoided. These compounds should not be administered within a period of 14 days before or after treatment with the veterinary medicinal product.

#### **4.9. Dosage and administration route**

##### **Cattle and Sheep:**

The veterinary medicinal product should be administered as an oral drench. Dosing may be carried out using a drenching bottle or a suitable gun system, at a rate of 7.5 mg levamisole hydrochloride/kg bodyweight and 15 mg Oxyclozanide/kg, achieved by administering 50 ml per 100 kg bodyweight in cattle and 5 ml per 10 kg bodyweight in sheep.

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

If recommended dosages are exceeded animals may exhibit signs of over dosage. The effects of levamisole over dosage include impaired motor function i.e. muscle tremors, head shaking and increased salivation. These effects are transient and more likely to be found in cattle than in sheep. The effects of Oxyclozanide over dosage are dullness and some loosening of feces in sheep and possible diarrhea, in appetite and loss of weight in cattle. The effects are occasionally enhanced in animals with severe liver damage and/or dehydration at the time of dosing.

#### **4.11. Special restrictions for use and special conditions for 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:**

##### **Cattle:**

Meat and offal: 28 days.

##### **Sheep**

Meat and offal: 10 days.

Animals must not be slaughtered for human consumption during treatment.

Not authorized for use in animals producing milk for human consumption.

## **5. PHARMACOLOGICAL PROPERTIES**

ATCvet code: **QP52AE51**

### **5.1. Pharmacodynamic properties**

Levamisole is an imidazothiazole that acts by interfering with parasite nerve transmission causing muscular paralysis. It is effective against adult and immature gastro-intestinal roundworm and lungworm infections. Oxyclozanide is a salicylanilide which is mainly active against adult liver flukes. It is distributed to the liver, kidney and intestines and is excreted in the bile.

## **5.2. Pharmacokinetic information**

Levamisole's rapid absorption and short half-life are ideal for treating parasites that are susceptible to a quick, high concentration of the drug.

Oxyclozanide's slower absorption and long half-life provide a more sustained level of the drug in the system, which is effective for targeting parasites like liver flukes that require longer exposure to the drug.

## **6. PHARMACEUTICAL INFORMATION**

### **6.1 List of excipients**

Sodium metabisulphite 0.15 mg/ml  
Tartrazine 0.11 mg/ml  
Sodium methyl parahydroxybenzoate 1.8 mg/ml  
Sodium citrate  
Anhydrous citric acid  
Disodium edetate  
Polysorbate 80  
Xanthan gum  
Antifoam M30  
Purified water

### **6.2 Incompatibilities**

None known.

### **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 immediately, 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**

HDPE bottle with plastic cap and induction seal, Packed in Cardboard box.

**Pack size:** 250ml & 1 Liter

### **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.: 014524
- 9. DATE OF FIRST AUTHORISATION**  
Date of Reg.: 07-12-1993
- 10. DATE OF REVISION OF THE TEXT**  
31-01-20