PAMEZAN DRENCH

(Levamisole, Oxyclozanide, Cobalt Sulphate & Selenite Sodium)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PAMEZAN DRENCH

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Levamisole …….. 1.500gm
Oxyclozanide …….. 3.000gm
Cobalt Sulphate …….. 0.382gm
Selenite Sodium …….. 0.035gm

3. PHARMACEUTICAL FORM

Oral Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Sheep & Cattle.

4.2. Indications for use specifying the target species

For the treatment and control of both gastro-intestinal and pulmonary nematode infections and adult liver fluke infections in cattle and sheep. The veterinary medicinal product should be used in cases of parasitic gastroenteritis and lungworm caused by those organisms sensitive to treatment with Levamisole hydrochloride.

Levamisole is effective against mature and developing immature stages of a wide range of important nematode species and is highly effective against the following:
Lungworms:
Dictyocaulus spp.
Gastrointestinal worms:
Trichostrongyles spp.
Cooperia spp.
Ostertagia spp. (except inhibited Ostertagia larvae)
Haemonchus spp.
Nematodirus spp.
Bunostomum spp.
Oesophagostomum spp.
Chabertia spp.

The veterinary medicinal product also removes most mature Fasciola spp. (flukes) present in the bile ducts of the liver.

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):	Diarrhoea1 Increased bowel movements (frequency)1 Inappetence1
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Photosensitisation2 Skin inflammation2 Skin slough3

1 Transient.
2 Particularly non pigmented skin e.g., muzzle, udder and which may be painful.
3 In severe cases of photosensitization.
Species: Sheep

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic-type reaction1 Swelling1

1 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 appetence 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. With drawl 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. Selenium's primary function is as a component of selenoproteins, which are enzymes that perform a variety of crucial roles. Many selenoproteins, such as glutathione peroxidase and thioredoxin reductase, have potent antioxidant properties, protecting cells from oxidative damage. The pharmacodynamic effects of cobalt are largely related to its role in vitamin B12 synthesis. However, in supra-physiological doses, it can exert additional effects

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. Selenium is an essential trace element. After ingestion, it's absorbed in the small intestine and then widely distributed throughout the body, with high concentrations found in the liver and kidneys. The absorption efficiency can vary depending on the form of selenium (e.g., L-selenomethionine is absorbed more efficiently than inorganic selenite). Once in the body, it is metabolized into various compounds, including selenophosphate and selenocysteine, which are the building blocks for selenoproteins. Selenium is primarily eliminated through the kidneys in the urine, but some is also excreted in the feces. The half-life can be quite long, and chronic exposure can lead to accumulation in the body. Cobalt is an essential component of vitamin B12 (cobalamin), which is crucial for red blood cell formation and neurological function. It's absorbed through the gastrointestinal tract, and the absorption rate can be highly variable and influenced by factors like nutritional status and the specific form of cobalt. After absorption, it is distributed to various tissues, with the highest concentrations found in the liver, kidneys, and spleen. The elimination of cobalt is primarily through the kidneys in the urine, but also through feces. The half-life of cobalt can be prolonged, especially for insoluble forms that may accumulate in the lungs after inhalation.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Sodium metabisulphite (E223)
Tartrazine (E102)
Sodium methyl parahydroxybenzoate (E219)
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

Plastic bottles (polypropylene) with plastic cap and induction seal.
Pack size: 100ml, 500ml & 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.: 025754

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 07-06-2000

10. DATE OF REVISION OF THE TEXT

31-01-2025

NAWAN LABORATORIES (PVT) LTD.
136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.