CEREX DRENCH
(Levamisole HCl, Triclabendazole)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CEREX DRENCH

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml Contains:
Levamisole HCl …….. 3.750gm
Triclabendazole ……. 5gm

3. PHARMACEUTICAL FORM

Oral Suspension.

4. CLINICAL INFORMATION

4.1. Target species

Camel, Cattle, Sheep & Goat

4.2. Indications for use specifying the target species

For the treatment of infestations of:
Lungworm: Dictyocaulus spp.;
- Roundworm: Trichostrongylus spp., Cooperia spp., Ostertagia spp., Haemonchus spp., Nematodirus spp., Bunostomum spp., Oesophagostomum spp., Gaigeria spp., en Chabertia spp.;
Liverfluke: Fasciola hepatica.

4.3. Contraindications

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

4.4. Special warnings for each target species

The following situations should be avoided as they may promote the development of resistance promote and may ultimately lead to treatment that is not effective: too frequent and repeated use of anthelmintics from the same group over a prolonged period - underdosing, due to underestimation of body weight, incorrect administration of the veterinary medicinal product or a non-calibrated or incorrectly calibrated dosing device (if applicable).

Suspected clinical cases of resistance to anthelmintics should be further investigated by using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the result of the tests is clearly suggestive of resistance to a particular anthelmintic, an anthelmintic from another class having a different mode of action should be administered

Resistance to levamisole in Teladorsagia, Cooperia and Trichostrongylus species in sheep has been reported in a number of countries, including within the EU. Resistance in Haemonchus in sheep has been reported outside the EU. Resistance to triclabendazole in Fasciola species in small ruminants has been reported in a number of countries, including within the EU. Therefore, the use of this veterinary medicinal product should be based on national epidemiological data (regional and farm level) regarding the susceptibility of these worm species and advice should be given on how to limit further development of resistance to anthelmintics.

4.5. Special precautions for use

Special precautions for use in animals:

Clean drenching tools before and after use
As with any husbandry procedure, care should be taken when handling the animals especially when inserting the dosing gun nozzle into the animal's mouth. Unnecessary force should not be used as this may cause damage to the mouth and pharyngeal region.
Equipment should be thoroughly cleaned before and after dosing. Do not exceed the stated dose.

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)

Lacrimation, salivation, hyperesthesia, nervous symptoms and colic.

4.7. Use during pregnancy and lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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

None known.

4.9. Dosage and administration route

Oral administration. 10 mg triclabendazole and 7.5 mg levamisole hydrochloride per kg body weight, corresponding to 1 ml of the veterinary medicinal product per 5 kg body weight.
Depending on the body weight of the sheep, the dosage of the veterinary medicinal product is as follows:

Weight	Quantity in ml
10 kg	2
15 kg	3
20 kg	4
30 kg	6
40 kg	8
50 kg	10
60 kg	12

+ 2 ml for each additional 10 kg.
For correct dosage, body weight should be determined as accurately as possible; the accuracy of the dosing aid should be checked.
When animals are treated in groups rather than individually, they should be grouped according to weight and the dose to be administered should be calculated accordingly to avoid under- or overdosing.
The veterinary medicinal product can be administered by means of a manual or automatic application device Shake container thoroughly before use and use undiluted veterinary medicinal product from the original container

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

In case of overdose, no other side effects are known than those mentioned under section 4.6

4.11. Withdrawal period:

Meat and offal: 42 days.
Not permitted for use in ewes producing milk for human consumption, including during the dry period. Do not use within 1 year prior to first lambing in ewes intended to produce milk for human consumption

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics; levamisole, combinations
ATCvet code: **QP52AE51**

5.1. Pharmacodynamics properties

Triclabendazole is an anthelmintic and belongs to the chemical class of benzimidazoles. The mechanism of action of triclabendazole is not known. It is probably different from that of other benzimidazoles as it does not show tubulin associated activity. Triclabendazole and its sulfoxide metabolite are active against Fasciola spp. The mechanism of action of levamisole is based on an interaction with cholinergic receptors of susceptible helminths. Levamisole also inhibits the enzyme succinate dehydrogenase which results in a disruption of ATP synthesis. This eventually leads to paralysis and excretion of the worm.

5.2 Pharmacokinetic information

After oral administration, triclabendazole is readily and almost completely absorbed from the gastrointestinal tract. The absorbed triclabendazole is then almost completely oxidized in the liver, with the only or major metabolites detectable in the blood being triclabendazole sulfoxide and sulfone.
Triclabendazole sulfoxide reaches peak concentrations (approximately 10 ppm) 1 day after administration of the veterinary medicinal product and the sulfone metabolite reaches peak concentrations (approximately 15 ppm) 3 days after administration. Both metabolites are highly bound to plasma proteins, particularly albumin. Levamisole is well absorbed from the gastrointestinal tract with peak blood levels after 4-6 hours in sheep. Levamisole

is extensively metabolized in the liver to form five metabolites that are all excreted in urine and feces. Levamisole is also excreted in milk in lactating animals

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

In the absence of incompatibility studies, this medicinal product must not be mixed with other 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 1 Year, do not store.

6.3. Special precautions for storage

Store below 25 °C.
Protect from light.
Keep out of reach and sight of children
Discard unused product.
To be used as directed by the registered veterinary practitioner only.

6.4. Nature and composition of primary conditioning

White HDPE bottles with a capacity of 100ml, 150ml, 500ml, 1 Liter with a Red screw cap.

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.: 026415

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 14-10-2000

10. DATE OF REVISION OF THE TEXT

05-01-2025