ZOSTER ORAL SUSPENSION

(Triclabendazole, Oxfendazole)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zoster Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Triclabendazole ……..…85 mg
Oxfendazole ……..….22.65 mg

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

Zoster Oral Suspension is a broad spectrum anthelmintic for the treatment and control of mature and developing immature gastro-intestinal roundworms and lungworms and also tapeworms in cattle and sheep, for the treatment and control of adult, immature and early immature stages of liver fluke (Fasciola hepatica) susceptible to triclabendazole.

For the treatment of cattle and sheep infested with benzimidazole susceptible strains of the following species:
GASTRO-INTESTINAL ROUNDWORMS: Ostertagiaspp., Haemonchusspp., Nematodirusspp., including N. battus, Trichostrongylus spp., Cooperiaspp., Bunostomumspp., Oesophagostomumspp., Chabertiaspp., Capillariaspp., Trichurisspp..
LUNGWORMS: Dictyocaulus spp.
TAPEWORMS: Monieziaspp.
In cattle it is also effective against inhibited larvae of Cooperiaspp. usually effective against inhibited/arrested larvae of Ostertagiaspp.. In sheep it is effective against inhibited/arrested larvae of Nematodirusspp, benzimidazole susceptible Haemonchusspp. Ostertagiaspp.

4.3. Contraindications
Do not use in case of hypersensitivity to the active substances or to any of the excipients.
Do not use in sheep producing milk for human consumption.

4.4. Special warnings for each target species

The following situations should be avoided as they promote the development of resistance and may ultimately lead to treatment ineffectiveness:
Repeated use of anthelmintic from the same class over a long period of time
Under dosing, 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.

Therefore, the use of this veterinary medicinal product should be based on national epidemiological data (regional and farm level) regarding the susceptibility of parasites 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:

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)

No Side Effect shown

4.7. Use during pregnancy and lactation or lay

The product is safe for use during pregnancy and lactation. However, the product is not permitted for use during lactation in animals producing milk for human consumption

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

None known

4.9. Dosage and administration route

For oral administration only.
Shake well before use.

Camels, Cattle, Sheep & Goats: 1ml per 8 kg Body weight.
For correct dosage, body weight should be determined as accurately as possible; the accuracy of the dosing aid should be checked.

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

Symptoms of overdose have not been observed at 3 and 5 times the recommended dose. However, if they do occur, they are consistent with the mechanism of action of Oxfendazole and/or triclabendazole and will manifest as transient salivation, depression, drowsiness, ataxia and decreased food intake, 8 to 12 hours after treatment. Treatment is generally not necessary and recovery is usually complete within 1 to 5 days. There is no specific antidote.

4.11. Withdrawal period:

Meat: 31 days
Milk: Not approved 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: Antiparasitic product, Endectocide
ATCvet code: **QP52AC30**.

5.1. Pharmacodynamic properties

Oxfendazole, (methyl [5-phenylsulphinyl-1-H-benzimidazole-2-yl] carbamate), belongs to a class of compounds, the benzimidazoles. The Benzimidazoles possess anti-mitotic properties, and this action is related to their capacity to bind to tubulin leading to inhibition of formation of microtubules. This, in turn, leads to disruption of cell division. Eventually cell lysis and disintegration occur. Oxfendazole may concentrate preferentially in intestinal cells of parasites to exert its toxic effects initially and principally at this site. Similar effects do not occur in host cells, possibly because of differential binding characteristics. The disruption of parasite metabolic processes, and the effects of oxfendazole on enzymes of helminth parasites, involves inhibition of glucose and sodium uptake, reduced muscle glycogen content, uncoupling of oxidative phosphorylation and inhibition of malate dehydrogenase and fumarate reductase

Triclabendazole is a flukicide belonging to the benzimidazole group of anthelmintics. It has been established that benzimidazole anthelmintics selectively bind to ÿ-tubulin and thereby cause the depolymerization of microtubules and the subsequent disruption of microtubule-based processes in helminths.

5.2. Pharmacokinetic information

Oxfendazole is a sulphoxide identical to the sulphoxide metabolite of fenbendazole, both are known to be anthelmintically active and metabolically interconvertible. Reduction of oxfendazole to fenbendazole occurs in the ruminal fluid while oxidation of fenbendazole

to oxfendazole is carried out by hepatic microsomal enzymes in the liver. Much of fenbendazole's anthelmintic activity is attributed to oxfendazole, the latter being much more potent.

The majority of the oral dose of triclabendazole is eliminated in rats, sheep, goats and rabbits in the faeces after 6-10 days, as unchanged drug or biliary excretion products. Urinary excretion is minimal. Sulfone, sulfoxide, ketones and 4-hydroxy-triclabendazole derivatives are the major metabolites identified in plasma.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed 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: 6 Month

6.3. Special precautions for storage

Store below 25°C
Protect from light.
Do not freeze.
Keep out of reach of Children.

6.4. Nature and composition of primary conditioning

Polyethylene containers with a polypropylene screw cap of 100ml & 1 liter.
Not all pack sizes may be marketed.

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.: 119874

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 23-01-2024

10. DATE OF REVISION OF THE TEXT

28-01-2025