

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of Veterinary Products

NILZASH S FORTE

[Levamisole HCl 3% and Oxyclozanide 6% Suspension

Each ml contains:

Levamisole HCl BP.....30 mg

Oxyclozanide BP.....60 mg

Approved colour used IH.....q.s.

Excipients..... q.s.

Flavoured syrupy base IH.....q.s.

2. Indication

For the treatment of Liver Flukes, Round worms and Lungworms in cattle, sheep & goats.

For the treatment and control of gastro-intestinal and pulmonary nematode infections and Chronic fascioliasis in Cattle, Sheep & Goat.

It removes mature and developing immature stages of a range of nematode species.

It is effective against the following worms and flukes :

In the abomasum: Haemonchus, Ostertagia and Trichostrongylus spp.

In the intestines: Trichostrongylus, Cooperia, Nematodirus, Oesphagostomum, Chabertia and Bunostomum spp.

In the lungs: Dictyocaulus spp. including D. viviparus larvae in Cattle.

It removes practically all flukes (Fasciola spp.) present in the bile ducts of the liver.

3. Activity

Levamisole is the laevo-enantiomer of tetramisole and is an anthelmintic imidazothiazole. It is effective upon oral, administration against various species of nematodes. Its anthelmintic action is characterised by paralysis of the worm through a neuromuscular inhibition of the depolarising type, leading to passive elimination of the worm.

Oxyclozanide is an anthelmintic of the salicylanilide group. It is effective against Fasciola species, acting as an uncoupler of oxidative phosphorylation. It may act at more than one site to decrease levels of ATP leading to metabolic malfunction and death of the parasite.

Levamisole is very rapidly absorbed and peak plasma concentrations are attained on within 1 to 3 hours after oral dosing. Levamisole is rapidly distributed to all tissues, where levels are several times higher than the corresponding plasma levels. Elimination from plasma and tissues is also very rapid, the main elimination routes being the urine.

Oxyclozanide is slowly absorbed after oral administration with peak plasma levels 24 hours after dosing. Excretion is predominantly faecal.

4. Dosage & Administration

For oral administration to sheep, goats and cattle at a dose rate of 7.5 mg Levamisole HCL and 15 mg Oxyclozanide per kg body weight.

Body Weight (kg)	Dose (ml)
Cattle- 2.5 ml per 10 kg body weight	
50	12.5
100	25
150	37.5
200	50
250	62.5
300	75

Sheep and Goats- 0.5 ml per 2 kg body weight	
10	2.5
20	5
30	7.5
40	10
50	12.5
60	15

5. Contraindications

Do not use in animals producing milk for human consumption.
NILZASH S FORTE is safe for pregnant, lactating and young stock, especially the immuno-compromised ones.

6. Warnings & Side Effects

Warnings & Precautions:

Keep out of reach of children.

Wash hands after use.

No particular precautions are required however in weak and debilitated animals divided doses are recommended. Any change in dose should be done in consultation with the veterinarian.

Side Effects:

Over dosage can cause excitation, lachrymation, sweating, excessive salivation, coughing, hyperpnoea, vomiting, colic and spasms.

7. Withdrawal Period

NILZASH S FORTE should not be used in sheep, goats and cattle producing milk for human consumption.

Milk for human consumption may only be taken after 72 hours from last treatment. Do not slaughter animals for human consumption during the treatment. Animals may be slaughtered for human consumption after 28 days from last treatment.

8. Storage Conditions

Store below 30°C in a dry place, protect from direct sunlight.

9. Presentation

100 ml, 500 ml and 1000 ml

10. Marketing Authorization Holder

ASHISH LIFE SCIENCE PVT LIMITED
J-137, M.I.D.C, Tarapur, Boisar-401501, Tal and Dist – Palghar
Maharashtra, India

11. Marketing Authorization Number

Rwanda FDA-VMP-MA-009