PAMECTIN INJECTION
(Ivermectin 1%)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PAMECTIN INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml contains:
Ivermectin ……. 1gm

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and sheep.

4.2 Indications for use, specifying the target species

Indicated for the effective treatment and control of the following parasites of cattle and sheep:

CATTLE
PARASITE
Gastrointestinal Roundworms
Ostertagia lyrata
Ostertagia ostertagi
Cooperia oncophora
Cooperia pectinata
Cooperia punctata
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus
Nematodirus helvetianus
Nematodirus spathiger
Trichuris spp.

Lungworms
Dictyocaulus viviparous

Eye Worms
Thelazia spp

Warbles
Hypoderma bovis
H. lineatum

Mange Mites
Psoroptes ovis
Sarcoptes scabei var. bovis

Sucking Lice
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

The product may also be used as an aid in the control of biting lice (Damalinia bovis) and the mange mite Chorioptes bovis, but complete elimination may not occur.

Persistent Activity
Given at the recommended dosage of 1ml per 50kg bodyweight, the product controls re-infection with the following nematodes up to the duration shown:

Parasite	**No. of Days After Treatment**
Barbers pole worm - *Haemonchus placei*	14
Small intestinal worm - *Cooperia spp.*	14
Hairworm – *Trichostrongylus axei*	14
Brown stomach worm - *Ostertagia ostertagi*	21
Nodular worm - *Oesophagostomum radiatum*	21
Lungworm – *Dictyocaulus viviparous*	28

The timing of treatment should be based on epidemiological factors and should be customized for each individual farm. A dosing program should be established by a qualified professional person.

SHEEP
PARASITE
Gastrointestinal Roundworms
Ostertagia circumcincta
O. trifurcata
Haemonchus contortus
Trichostrongylus axei
T. colubriformis
T. vitrinus
Cooperia curticei
Oesophagostomum columbianum
O. venulosum
Nematodirus filicollis
Chabertia ovina
Trichuris ovis

Lungworms
Dictyocaulus filaria
Protostrongylus rufescens

Nasal Bots
Oestrus ovis

Mange Mites
Psoroptes ovis*
Benzimidazole-resistant strains of Haemonchus contortus and Ostertagia circumcincta are also controlled.

4.3 Contraindications

Do not inject intravenously or intramuscularly.

The product is specifically for use in the target species. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.

4.4 Special warnings for each target species

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 anthelmintics 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 (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to macrocyclic lactones (which includes ivermectin) has been reported in Teladorsagia spp. in sheep and in Cooperia spp. in cattle within the EU. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

i. Special precautions for use in animals

When treating groups of animals use only an automatic dosing device
(with vented draw off apparatus when using the 50ml vial).
Syringes must be filled from the vial through a dry sterile draw-off needle that has been placed in the vial stopper. Vial stoppers must not be broached more than 20 times.

Sheep scab (Psoroptes ovis) is an extremely contagious external parasite of sheep. To ensure complete control great care must be taken to avoid re–infestation, as mites may be viable for up to 15 days off the sheep. It is important that all sheep which have been in contact with infected sheep are treated. Contact between treated, infected and untreated flocks must be avoided until at least seven days after treatment.

In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although clinical improvement may be seen, elimination of all mites may not occur.

This product does not contain any antimicrobial preservative.
Swab septum before removing each dose. Use a sterile needle and syringe.

ii. Special precautions to be taken by the person administering the medicinal product to the animals

Do not smoke, drink or eat while handling the product. Wash hands after use.
Take care to avoid self-injection: the product may cause local irritation and/or pain at the site of injection.
In case of accidental self-injection, seek medical advice and show the label or package leaflet to the physician.

4.6 Adverse reactions (frequency and seriousness) Cattle
Mild and transient discomfort has occasionally been observed in cattle following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed.

Sheep
Discomfort, sometimes intense but usually transient, has been observed in some sheep following subcutaneous administration.

In both species these reactions disappear without treatment.

4.7 Use during pregnancy, lactation or lay

Ivermectin can be administered to cows and ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It can be used in breeding ewes, rams, bulls and cows without affecting fertility. Ivermectin can be given to all ages of animals including young calves and lambs.

4.8 Interaction with other medicinal products and other forms of interaction

Ivermectin has been used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.
Adequate vaccination of sheep against clostridial infections is strongly recommended.

4.9 Amounts to be administered and administration route

Ivermectin should be given only by subcutaneous injection, using aseptic precautions, at the recommended dosage level of 200 mcg ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and in the neck in sheep.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Use this chart as a guide in working out the appropriate dose rate:

CATTLE (1ml/50kg)		**SHEEP** (0.5ml/25kg)	
Bodyweight (kg)	**Dose Volume (ml)**	**Bodyweight (kg)**	**Dose Volume (ml)**
Up to 50	1.0	Up to 5	0.1
51 – 100	2.0	5.1 – 10	0.2
101 – 150	3.0	10.1 – 15	0.3
151 – 200	4.0	15.1 – 25	0.5
201 – 250	5.0	25.1 – 50	1.0
251 – 300	6.0	50.1 – 75	1.5
301 – 350	7.0	75.1 - 100	2.0

351 – 400	8.0

For cattle weighing over 400kg calculate the dose at the rate of 1ml per 50kg bodyweight

For sheep weighing over 100kg calculate the dose at the rate of 0.5ml per 25kg.

When treating sheep of less than 16kg, seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml. For the treatment of individual sheep, a syringe not exceeding 2.0ml and calibrated in increments of 0.1ml should be used.

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of a sterile 17 gauge x ½ inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended.

For the treatment and control of sheep scab, two injections with a seven day interval are required to treat clinical signs of scab and to eliminate mites.

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

Cattle
Single doses of 4.0 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression.
No antidote has been identified, however, symptomatic therapy may be beneficial.

Sheep
Dose levels up to 4 mg ivermectin per kg (20 x the use level), given subcutaneously, resulted in ataxia and depression.

4.11 Withdrawal periods

Cattle (meat & offal): 49 days
Cattle (milk): Do not use in cattle producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant heifers, within 60 days of calving.

Sheep (meat & offal): 37 days
Sheep (milk): Do not use in sheep producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code:
QP54AA01

5.1 Pharmacodynamics properties

Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

5.2 Pharmacokinetic properties

Maximum plasma concentration

Cattle
At a dose level of 0.2 mg ivermectin per kg a maximum plasma concentration of
35-50 ng/ml is reached in about 2 days and the half-life in plasma is 2.8 days. It is also established that ivermectin is carried mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Sheep
At a dose level of 0.3 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.

Excretion: length of time and route

Cattle
A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.3 mg ivermectin per kg, the liver (target tissue) had residues ranging from 454 ppb at 2 days post treatment to 11 ppb at 28 days post treatment. All other tissues had lower residues at all time periods: fat kidney muscle.

The injection site had residues shortly after treatment, ranging up to 69 ppm at 2 days withdrawal, but by 28 days the average residue was negligible (2 ppb). Cattle receiving a single dose of tritium-labelled ivermectin (0.2 - 0.3 mg/kg bodyweight) were slaughtered at 7, 14, 21 and 28 days after dosing.

Composites of faeces collected during the first 7 days after dosing contained almost all the dosed radioactivity. Only about 1-2 % of the dosed radioactivity was excreted in the urine.
Analyses of the faeces showed that about 40-50% of the excreted radioactivity was present as unaltered drug. The remaining 50-60% was present as metabolites or degradation products almost all which were more polar than the ivermectin.

Sheep
A liquid chromatographic method with fluorescence detection allows the determination of ivermectin residues in tissues. After an injection of 0.3 mg ivermectin per kg, the liver (target tissue) had residues ranging from 160 ppb at 3 days post treatment to 7.2 ppb at 28 days post treatment. The highest residue levels were recovered in fat (from 230 ppb at 3 days post treatment to 13 ppb at
28 days post treatment). Residues in all tissues were below 30 ppb at 28 days post treatment. Radioactive ivermectin was administered to sheep at a dose rate of 0.3 mg per kg. Analyses of the feces showed that about 99% of the drug and its metabolites are excreted in the feces, about 1 % being excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

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: use within 28 days, do not store.

6.3 Special precautions for storage

Store below 30°C.
Protect from light and moisture
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

Following withdrawal of the first dose, use the product within 6 months. Discard unused material.

6.4 Nature and composition of immediate packaging

50ml amber glass vial, with a rubber stopper and aluminium flip off-seals.
100ml amber glass vial, with a rubber stopper and aluminium flip off-seals.

6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Container disposal:

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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.: 025758

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 07.06.2000

10. DATE OF REVISION OF THE TEXT

05-06-2024

MANUFACTURED BY:
NAWAN LABORATORIES (PVT) LTD.
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