1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Structure of the Summary of Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Generic name: Ivermectin injection 1%

Brand name: Sinomectin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:

Ivermectin: 10mg;

Glycerol formal: 0.15ml;

Propylene glycol: Add up to 1ml.

3. PHARMACEUTICAL FORM

Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ivermectin is indicated for the treatment of infestations caused by the following ecto- and endoparasites sensitive to ivermectin:

Round gastrointestinal worms
Ostertagia lyrata (Adult, L4)
Haemonchus placei (Adult, L3, L4)
Trichostrongylus axei (Adult,L4)
Trichostrongylus colubriformis (Adult,L4)
Cooperia oncophora (Adult,L4)
Cooperia punctata (Adult,L4)
Cooperia pectinata (Adult, L5)
Oesophagostomum radiatum (Adult,L3, L4)
Nematodirus helvetianus (Adult)
Nematodirus spathiger (Adult)
Bunostomum phlebotomum (Adult, L3, L4)
Adult and inhibited forms of *Ostertagia ostertagi*.

Lungworms
Dictyocaulus viviparus (Adult, L4)

Warble flies (all parasitic stages)
Hypoderma bovis, H lineatum

Sucking lice
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Mange and other acariosis produced by:

Acari
Psoroptes ovis (syn. *P. communis* var. B*ovis*)
*Sarcoptes scabiei (*var. *bovis*)

Ivermectin injection helps in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur

4.2 Posology and method of administration

For single treatment only. It should be injected subcutaneously

Bodyweight and dosage should be accurately determined prior treatment to avoid underdosing.

Ivermectin should be administered at a dose of 200 µg/kg bodyweight (equivalent to 1ml/50 kg bodyweight).

It should be injected subcutaneously in front of or behind shoulder using aseptic technique. The use of a needle 16 gauge x 15 to 20 mm long is suggested. Use sterile equipment.

The maximum volume administered per injection site must not exceed 3.5ml.

Equivalent to:

Weight (kg)	Dose (ml)
Up to 50	1
51 – 100	2
101 – 150	3
151 – 200	4
201 – 250	5
251 – 300	6
301 – 350	7
351 – 400	8
401 – 450	9
451 – 500	10
501 – 550	11
551 - 600	12

Duration of the effect:

Ostertagia spp.: at least 7 days has been substantiated

Dictyocaulus viviparus: at least 14 days has been substantiated

4.3 Contraindications

Do not use in lactating dairy cows producing milk for human consumption.

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

Avermectins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs - especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

Do not use in cats and dogs as severe adverse reactions may occur.

Do not use in cases of known hypersensitivity to the active ingredient

Do not administer by intramuscular or intravenous route.

4.4 Special warnings and special precautions for use

i) Special precautions for use in animals

Contact with treated and non-treated infected herds must be avoided at least seven days after the treatment.

The product is effective in all hypodermosis stages, however, it is very important to treat on time (at the end of warble fly season). The elimination of Hypoderma larvae may cause negative reactions on the host, when they are found in vital areas. Killing Hypoderma lineatum, if found in perioesophageal tissue, may cause salivation and tympanism. Killing Hypoderma bovis, if found in the vertebral canal, may cause unsteadiness or paralysis. Bovine should be treated before or after those stages of warble flies.

Frequent and repeated use of ivermectin may develop resistances.

As ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

ii) Special precautions to be taken by the person administering the medicinal products to animals

Do not smoke, eat or drink while handling the product.

Direct contact with the skin should be avoided.

Take care to avoid self-injection. Inadvertent self-injection may result in local irritation and/or pain at injection site. In case of accidental self-injection seek medical advice immediately and show the package insert or the label to the physician.

If product is spilled, avoid its contact with eyes, wounds or inflamed skin.

It is advisable to wash with plenty of water.

4.5 Interaction with other FPPs and other forms of interaction

Ivermectin activity *in vitro* is enhanced by benzodiazepin derivates

4.6 Pregnancy and lactation

Do not use in lactating dairy cows producing milk for human consumption.

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

Not known.

Post-marketing experience (for example)

4.9 Overdose

A single dose of 4.0 mg of ivermectin/kg given subcutaneously (20x recommended dose rate) to bovines caused ataxia and depression.

If overdose occurs, apply symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ivermectin is an internal broad-spectrum and external antiparasitic of the avermectin family, which is produced by the fermentation of Streptomyces avermitilis

Pharmacotherapeutic group: endectocide

ATCVet code: QP54AA01

Ivermectin is a member of the macrocyclic lactones class of endectocides. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels, which occur in invertebrate nerves 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 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-gate 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.

Resistances

The resistance mechanism to Ivermectin is not completely determined. Its appearance is associated to modifications in the channels of the chloride ion dependent on glutamate, increasing the number in the binding sites to glutamate and to the increased expression of a membrane P-glycoprotein, which possibly would avoid reaching active concentrations of the ivermectin in the resistant parasite. The resistance to Ivermectin has also been related to a reduction in the cuticle permeability of the nematodes resistant to this drug.

There is cross-resistance with other avermectins and with milbemycin.

5.2 Pharmacokinetic properties

After subcutaneous administration of the recommended dose of Ivertin to cattle (0,2 mg Ivermectin / kg), the following parameters were observed: Cmax of 44 ng/ml (range: 25.6 – 72.5), tmax of 88 h, and AUC of 9702 ng·h/ml. It is also established that Ivermectin is carried mainly in plasma (80 %). This distribution between plasma and blood cells remains relatively constant.

In cattle, only about 1-2 % is excreted in urine; the remainder is excreted in faeces, approximately 60% are excreted as unaltered drug. The remainder is excreted as metabolites or degradation products. Maximum residues are found in liver and fat, as parent compound with minor polar metabolites

Absorption

Distribution

Biotransformation

Elimination

Characteristics in patients

5.3 Preclinical safety data

The preclinical safety data shows that the product is well tolerated and safe when used as per the recommended dose for the intended disease in targeted animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol formal

Propylene glycol

6.2 Incompatibilities

Have not been described.

6.3 Shelf life

Shelf life: 36 months

Expiry date, once the product is opened: 28 days

6.4 Special precautions for storage

Store below 30ºC.

Keep vials in the outer carton.

6.5 Nature and contents of container

Pack size:

Polypropylene vials of 100ml+10ml, 50ml+5ml

6.6 Instructions for use and handling <and disposal>

Any unused product or waste material should be disposed of in accordance with national requirements.

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used containers.

7. MARKETING AUTHORISATION HOLDER

HEBEI NEW CENTURY PHARMACEUTICAL Co., Ltd.

8. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

05.2023