Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Kilo-mec 1% Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	
Ivermectin	10 mg
Excipient	
Benzyl alcohol (preservative)	10 mg

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep, cattle and pigs.

4.2 Indications for use, specifying the target species Cattle:

For the treatment of gastrointestinal nematodes, lungworms, eyeworms, warble flies, mites and lice (as shown below) of beef and non-lactating dairy cattle:

Gastrointestinal worms (adults and 4th stage larvae):
Ostertagia ostertagi Ostertagia lyrata Haemonchus placei Trichostrongylus colubriformis Cooperia oncophora (adults) *Cooperia punctata* (adults) *Cooperia pectinata* (adults) *Bunostomum phlebotonum Oesophagostomum radiatum*

Lungworms (adult and 4th stage larvae):
Dictyocaulus viviparus

Eyeworms (adult):
Thelazia spp.

Warble flies (parasitic stages):
Hypoderma bovis
H. lineatum

Mites:
Psoroptes ovis
Sarcoptes scabiei var. *bovis*

Sucking lice:
Linognathus vituli Haematopinus eurysternus Solenopotes capillatus

May also be used as an aid in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur. Treatment with Ecomectin 10 mg/ml Solution for Injection at the recommended dose rate prevents

re-infection with
Haemonchus placei, Cooperia oncophora, Cooperia pectinata and *Trichostrongylus axei* for 7 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* for 14 days after treatment and *Dictyocaulus viviparus* for 21 days after treatment.

Sheep

For the treatment of psoroptic mange (sheep scab), gastrointestinal nematodes, lungworms and nasal bots of sheep:

Gastrointestinal roundworms (adults):
Ostertagia circumcincta Haemonchus contortus Trichostrongylus axei
T. colubriformis and *T. vitrinus Cooperia curticei Nematodirus filicollis*
Variable activity may be observed against *Cooperia curticei* and *Nematodirus filicollis.*

Lungworms:
Dictyocaulus filaria (adults)

Mange mites:
Psoroptes ovis

Nasal bot:
Oestrus ovis (all larval stages)

Pigs

For the treatment of gastro-intestinal nematodes, lungworms, lice and mange mites of pigs.

Gastro-intestinal worms (adult and fourth stage larvae):
Ascaris suum Hyostrongylus rubidus Oesophagostomum spp.
Strongyloides ransomi (adults).

Lungworms:
Metastrongylus spp. (adults)

Lice:
Haematopinus suis

Mange Mites:
Sarcoptes scabiei var. *suis*

4.3 Contraindications

Do not use in lactating dairy cows and sheep producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers or non-lactating dairy sheep within 60 days of calving/lambing.
Do not use in cases of known hypersensitivity to ivermectin. Do not administer by the intravenous or intramuscular route.

4.4 Special warnings for each target species

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.

Sheep scab (*Psoroptes ovis*) is an extremely contagious external parasite of sheep. Following treatment of

infected sheep 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 to ensure all sheep which have been in contact with infected sheep are treated. Contact between treated infected and non-treated,
non-infected flocks must be avoided until at least 7 days after the last treatment.

4.5 Special precautions for use Special precautions for use in animals

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

Do not combine treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

The shedding of nematode eggs can continue for some time after treatment.

In Cattle: To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of warble fly activity and before the larvae reach their resting sites.

Frequent and repeated use may lead to the development of resistance. It is important that the correct dose is given in order to minimise the risk of resistance. To avoid under-dosing, animals should be grouped according to their bodyweight and dosed according to the dose of the heaviest animal in the group.

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

Do not smoke, eat or drink 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.

Swab septum before removing each dose.
When using the 200, 250 or 500 ml pack sizes, use only automatic syringe equipment. For the 50 ml pack size, use of a multiple dose syringe is recommended. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper.

4.6 Adverse reactions (frequency and seriousness)

Transitory discomfort has been observed in some animals immediately following subcutaneous administration. In cattle this may include jumping and rolling, but behaviour returns to normal after 15 minutes.
Soft tissue swelling and thickening of the skin at the injection site has been observed in treated animals. Typically these reactions are transient and disappear within one to four weeks.

4.7 Use during pregnancy, lactation or lay

The product can be administered during pregnancy in cows, ewes and sows. The fertility of males is not affected by administration of the product.

4.8 Interaction with other medicinal products and other forms of interactions

Do not combine ivermectin treatment with vaccination against lungworms. If vaccinated animals are to be treated, treatment should not be carried out within a period of 28 days before or after vaccination.

4.9 Amounts to be administered and administration route

For single administration only (except for the treatment of *Psoroptes ovis* infections insheep)

Cattle

Dosage:
1.0 ml per 50 kg bodyweight (based on a recommended dosage level of 200 micrograms ivermectin per kg bodyweight).

Administration:
Inject subcutaneously in front of, or behind, the shoulder using aseptic technique. A sterile 1.4 x 15 mm (17G x ½ inch) needle is recommended.

Sheep

Dosage:
0.5 ml per 25 kg of bodyweight (based on a recommended level of 200 micrograms ivermectin per kg bodyweight).

Administration:
For the treatment of gastrointestinal roundworms, lungworms and nasal bots inject once subcutaneously in the neck, using aseptic precautions; a sterile 1.4 x 15 mm (17G x ½ inch) needle is recommended. For the treatment of *Psoroptes ovis* (sheep scab), two injections with a seven day interval are required to treat clinical signs of scab and to eliminate living mites.

For young lambs weighing less than 20.0 kg give 0.1 ml per 5 kg. In these lambs the use of a syringe which can deliver as little as 0.1 ml is recommended.

Pigs

Dosage:
1.5 ml per 50 kg bodyweight (based on a recommended dosage level of 300 micrograms ivermectin per kg bodyweight)

Administration:
The recommended route of administration is by subcutaneous injection into the neck using aseptic technique and a sterile 1.4 x 15 mm (17G x ½ inch) needle .

For piglets weighing less than 16 kg give 0.1 ml per 3 kg. In these piglets the use of a syringe which can deliver as little as 0.1 ml is recommended.

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

Clinical symptoms of ivermectin toxicity include ataxia and depression. No antidote has been identified. In case of overdose, symptomatic treatment should be given. No signs of toxicity were observed in animals treated at up to 3 times the recommended dose rate.

Soft tissue swelling and thickening of the skin at the injection site has been observed in treated animals. Typically, these reactions are transient and disappear within four weeks.
Transitory discomfort has been observed in some animals, immediately following subcutaneous administration. In cattle this may include jumping and rolling, but behaviour returns to normal after 15 minutes.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows,

including pregnant dairy heifers, within 60 days of calving.

Sheep:
Meat and offal: 42 days.
Do not use in lactating ewes producing milk for human consumption. Do not use in sheep which are intended to produce milk for human consumption within 60 days of lambing.

Pigs:
Meat and offal: 28 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Ivermectin is a mixture of two partially modified compounds of abamectin belonging to the avermectin family, which are a macrocyclic lactone group of endectocides. Abamectin is a mixture of two fermentation products of the soil organism *Streptomyces avermitilis*.
ATC vet code: QP54AA01 Therapeutic group: Endectocide

5.1 Pharmacodynamic properties

Ivermectin is a macrocyclic lactone derivative and acts by inhibiting nerve impulses. It binds 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 relevant parasites. 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 particulars

In each of the target species the pharmacokinetic profile following subcutaneous administration was characterised as follows (pharmacokinetic parameters presented as mean values):

Following administration to cattle, Cmax was 51ng/ml, with a Tmax of 43 h, $T_{1/2}$ of 129 h and an AUC of 7398 ng.h/ml.

Following two subsequent administrations seven days apart to sheep, Cmax was 14 ng/ml, with a Tmax of 202 h, $T_{1/2}$ of 380 h and an AUC of 4686 ng.h/ml.

Following administration to pigs, Cmax was 6.35ng/ml, with a Tmax of 106 h, $T_{1/2}$ of 219 h and an AUC of 1260 ng.h/ml.

Only about 2% of the drug is excreted in urine, faecal excretion being the major route of elimination. Tissue residues of radioactivity following subcutaneous administration of tritium-labelled ivermectin are highest in liver and fat; lowest levels are found in brain.

In cattle, the residual antiparasitic effect of ivermectin is due to its persistence which in turn is due in part to its long intrinsic half life and its relatively high protein binding (90%).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol Ethanol
Water for Injection Propylene Glycol

6.2 Major incompatibilities

None known.

6.3 Shelf-life

The shelf life is 2 years from date of manufacture. Once broached the product should be used within 28 days.

6.4 Special precautions for storage

Store below 25°C in a dry place.
Protect form direct sunlight.
Keep container tightly closed Store in original carton.

6.5 Nature and composition of immediate packaging

HDPE multidose container with rubber stopper and aluminium ring. Pack sizes: 50 ml, 200 ml and 500 ml.

Clear PET multidose container with bromobutyl rubber stopper and aluminium cap.
Pack sizes: 50 ml, 250 ml and 500 ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with product or used container. Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

ECO Animal Health Europe Limited 6th Floor
South Bank House Barrow Street Dublin 4
D04 TR29
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22693/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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