Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Turbomec Injection for Cattle and Sheep, 1% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance
Ivermectin 1.0% w/v

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless, slightly viscous, non-aqueous sterile solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (Beef and non lactating cattle) and sheep.

4.2 Indications for use, specifying the target species

In cattle: treatment of the infections by the following parasites:

Gastro-intestinal roundworms (Adult and 4th stage larvae unless otherwise stated)
Ostertagia ostertagi
Ostertagia lyrata
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia oncophora
Cooperia punctata
Cooperia pectinata
Oesophagostomum radiatum
Nematodirus helvetianus (Adult only)
Nematodirus spathiger (Adult only)

Lungworms
Dictyocaulus viviparus. (adult and fourth stage larvae)

Warbles (parasitic stages):
Hypoderma bovis, H. lineatum

Mange mites:
Psoroptes ovis (syn. *P. communis* var. *bovis*)
Sarcoptes scabiei var. *bovis.*

Sucking lice:
Linognathus vituli
Haematopinus eurysternus

Sheep
In sheep: treatment of the infections by the following parasites:

Gastrointestinal roundworms (adult and fourth-stage larvae):
Teladorsagiacircumcincta including inhibited larvae
Teladorsagia trifurcata
Haemonchus contortus including inhibited larvae
Trichostrongylus axei (adults)
Trichostrongylus colubriformis and *Trichostrongylus vitrinus* (adults)
Cooperiacurticei
Oesophagostomum columbianum
O. venulosum (adults)
Nematodirus filicollis
Chabertia ovina
Trichuris ovis (adults).

Benzimidazole-resistant strains of *Haemonchus contortus* and *Teladorsagiacircumcincta* are also controlled.

Lungworms:
Dictyocaulus filaria (adult and fourth-stage larvae)
Protostrongylus rufescens (adults)

Nasal Bots (all larval stages)
Oestrus ovis

4.3 Contraindications

Do not use in cases of known hypersensitivity to Ivermectin.
Do not administer by the intravenous or intramuscular route.
Do not use in cats and dogs.

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.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device.

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 ivermectin has been reported in *Teladorsagia circumcincta* in sheep and *Ostertagia ostertagi* in cattle. Therefore, the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of these helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

Special precautions for use in animals

Before using a product containing ivermectin, seek professional advice on current use in recommendation to ensure good control of parasites and to limit further selection for resistance to anthelmintics.

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).

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. Consult your veterinarian on the correct timing of treatment.

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

Take care to avoid self-administration: the product may cause local irritation and/or pain at the site of injection.
Direct contact of the product with the skin should be kept to a minimum.
Do not smoke, eat or drink while handling the product.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Cattle
Transitory discomfort and a low incidence of soft tissue swelling have been observed at the injection site in some cattle following subcutaneous administration. These reactions have disappeared without treatment within 28 days.

Sheep
A transient pain reaction is often observed immediately following injection. Local injection site swelling has been observed in treated animals. Typically these reactions disappear without treatment.

4.7 Use during pregnancy, lactation or lay

Pregnancy
The product can be administered to beef cows and sheep at any stage of pregnancy

Fertility
Fertility is not affected by administration of the product.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Avoid underdosing. Assess bodyweight as accurately as possible before calculating the dosage.

A single administration of 0.5 ml per 25 kg bodyweight of cattle or sheep, corresponding to 200 µg ivermectin per kg bodyweight.

For young lambs weighing less than 20 kg, give 0.1ml per 5 kg. In these lambs, the use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

The administration should be given by subcutaneous injection under the loose skin in front or behind the shoulder in cattle or over the neck in sheep. The volume administered per injection site should not exceed 10 ml.

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

If animals are to be treated collectively rather than individually they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or over- dosing.
The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.

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.

Sheep
A dose level of 4 mg per kg (20 times the recommended treatment dose) given subcutaneously resulted in ataxia and depression. There is no known antidote. In case of overdose, symptomatic treatment should be given. No signs of systemic toxicity were observed in sheep treated with the product at up to 3 times the recommended dose rate.

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 sheep producing milk for human consumption. Do not use in sheep within 60 days of lambing where milk is to be used for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QP54AA01.
Pharmacotherapeutic Group: Endectocide.

5.1 Pharmacodynamic properties

Ivermectin belongs to the avermectin group. Ivermectin is a member of the macrocyclic lactone class of endectocides. 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-gates 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

Maximum plasma concentration

Cattle
At a dose level of 0.2mg ivermectin per kg a mean Cmax of 30.43 ng/ml is reached at a mean Tmax of 131 hours. It is also established that ivermectin is distributed mainly in the plasma (80%). This distribution between plasma and blood cells remains relatively constant.

Sheep
Following a single administration of the test product at a dose of 0.2 mg ivermectin per kg bodyweight, a mean maximum plasma concentration of 13.0 ng/ml was achieved at approximately four days after treatment.

Excretion: length of time and route

Cattle
Only about 1-2% is excreted in the urine the remainder is excreted in the faeces, approximately 60% of which is excreted as unaltered drug. The remainder is excreted as metabolites or degradation products. The major metabolite in cattle is 24-hydroxymethyl H2B1a and its fatty acid esters. Almost all of the metabolites of Ivermectin are more polar than the parent compound and no single minor metabolite accounts for more than 4% of total metabolites.

Sheep
Radioactive ivermectin was administered to sheep at a dose rate of 0.3 mg per kg. Analyses of the faeces showed that about 99% of the drug and its metabolites are excreted in the faeces, +/- 1% being excreted in the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Glycerol formal

6.2 Major incompatibilities

In the absence of compatability studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Multidose high-density polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and plain aluminium overseals, containing a clear, colourless sterile solution.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. The product should not enter water courses as this may be dangerous to fish and other aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/070/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of latst renewal: 01 June 2010

10 DATE OF REVISION OF THE TEXT

June 2019