Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Mectaject 1% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances
Ivermectin 1.0 % w/v

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to slightly yellow coloured solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, sheep and pigs.

4.2 Indications for use, specifying the target species

For the effective treatment and control of the following harmful parasites of cattle, sheep and pigs:

Cattle

Gastrointestinal roundworms (adult and fourth-stage larvae):
Ostertagia spp. (including inhibited *O. ostertagi*)
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia spp.
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
N. spathiger (adult)

Lungworms (adult and fourth-stage larvae):
Dictyocaulus viviparus

Eye worms (adult):
Thelazia spp.

Warbles:
Hypoderma bovis
H. lineatum

Mange mites:
Psoroptes bovis
Sarcoptes scabiei var. *bovis*

Suckling 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.

Persistent Activity
Treatment at the recommended dose rate controls re-infection with *Ostertagia* spp. and *Cooperia* spp. acquired up to 7 days after treatment and *Dictyocaulus viviparus* up to 14 days after treatment.

Sheep

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

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

Nasal Bots (all larval stages)
Oestrus ovis

Pigs

Gastrointestinal roundworms (adult and fourth-stage larvae):
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransomi (adult)

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.
Do not use by intramuscular or intravenous administration.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals
This product has been formulated specifically for use in cattle, sheep and pigs. It should not be used in other species as severe adverse reactions, including fatalities in dogs, may occur. 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.

(ii) Special precautions to be taken by the person administering the 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 or eat while handling the product.
Wash hands after use.

(iii) Other precautions
When using the 250 ml and 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)

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

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

Pigs
Mild and transient pain reactions may be seen in some pigs following subcutaneous injection.

All these reactions disappeared without treatment.

4.7 Use during pregnancy, lactation or lay

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

Lactation
Do not use in dairy cows or sheep producing milk for human consumption
Do not use in non-lactating dairy cows or sheep within 60 days of calving/lambing. The product can be used in sows at any stage of lactation.

Fertility
Fertility is not affected by administration of the product.

4.8 Interaction with other medicinal products and other forms of interactions

The product can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

4.9 Amounts to be administered and administration route

The product should be given only by subcutaneous injection at the recommended dosage level of 200 microgram ivermectin per kg bodyweight under the loose skin in front of, or behind, the shoulder in cattle and over the neck in sheep. At the

recommended dosage level of 300 microgram ivermectin per kg of bodyweight, the product should be given only subcutaneously in the neck of pigs.

Each ml contains 10 mg of ivermectin sufficient to treat 50 kg of bodyweight of cattle and sheep and 33 kg of bodyweight of pigs. The volume administered per injection site should not exceed 10 ml. The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 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. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw the product from the container.

In young pigs, especially those below 16 kg for which less than 0.5 ml of the product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

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

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
At dose levels up to 4 mg ivermectin per kg (20 x the use level) given subcutaneously resulted in ataxia and depression. No signs of systemic toxicity were observed in sheep treated with the product at up to 3 times the recommended dose rate, soft tissue swellings at the injection site were observed.

Pigs
A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbancy.

In case of overdose, symptomatic treatment should be given.

4.11 Withdrawal period(s)

Cattle(meat): 49 days.
Cattle (milk): 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): 42 days.
Sheep (milk): 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.
Pigs: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC vet code: QP54AA01
Therapeutic group Endectocide

5.1 Pharmacodynamic 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 particulars

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 ± 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 of 0.3 mg ivermectin per kg an average peak of 16 ng/ml is reached one day after injection.

Pigs
In pigs, at a dose level of 0.3 mg ivermectin per kg bodyweight, a mean Cmax of 6.87 ng/ml was reached at a mean Tmax of 86.75 hours, and the mean elimination half-life was 133.56 hours and the drug persisted in plasma for up to 28 days.

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.

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.

Pigs
Biliary excretion is also the major route of ivermectin excretion in pigs.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Glycerol formal

6.2 Major incompatibilities

None known.

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 precautions.

6.5 Nature and composition of immediate packaging

Multiple-dose polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and aluminium overseals.
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 product or waste material derived from the 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)

VPA22033/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 December 2000
Date of last renewal: 23 May 2007

10 DATE OF REVISION OF THE TEXT

June 2019