[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcimec 10 mg/ml solution for injection for pigs [IE]
Porcimec P 10 mg/ml solution for injection for pigs [BE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substance:
Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol
Glycerol formal

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful parasites of pigs:

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

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use by intramuscular or intravenous administration.
Do not use in cats and dogs as severe adverse reactions may occur.

3.4 Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal or herd.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test (FECRT)).

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authority.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The veterinary medicinal product has been formulated specifically for use in pigs only. It should not be administered to other species as severe adverse reactions may occur. 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Take care to avoid self-administration: the veterinary medicinal product may cause local irritation and/or pain at the site of injection.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:
See section 5.5.

3.6 Adverse events

Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site pain*

*Mild and transient discomfort has been observed in pigs following subcutaneous injection at injection site. All these reactions disappeared without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not administer the veterinary medicinal product during the first 40 days of pregnancy.

Fertility:
The veterinary medicinal product can be used in breeding sows and boars and will not affect fertility.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs. 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 hypodermic syringe, use a separate sterile needle to withdraw the veterinary medicinal product from the container.

In pigs, the recommended dosage level is 300 mcg ivermectin per kg bodyweight. This is equivalent to 1 ml per 33 kg bodyweight. The recommended route of administration is by subcutaneous injection into the neck.

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

It is important that the correct dose is given in order to minimise the risk of resistance. Assess bodyweight as accurately as possible before calculating the dosage.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Accuracy of the dosing device should be thoroughly checked.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 recumbency.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AA01

4.2 Pharmacodynamics

Ivermectin belongs to the avermectin group. 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.

4.3 Pharmacokinetics

At a dose level of 0.3 mg ivermectin per kg bodyweight, a mean Cmax of 6.94 ng/ml was reached at a mean T max of 86.75 hours, and the mean elimination half-life was 133.56 hours. Biliary excretion, followed by elimination in faeces is probably the major route for ivermectin excretion in pigs. While the major single component excreted was unaltered drug, the major metabolite in swine are 3'-0-desmethyl-H_2B_{1a} and 3'-O-desmethyl-H_2B_{1b}.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

Not all pack sizes may be marketed.

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

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: [DD/MM/YYYY]

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton – 50 ml, 250 ml & 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcimec 10 mg/ml solution for injection [IE]
Porcimec P 10 mg/ml solution for injection [BE]

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10 mg/ml

3. PACKAGE SIZE

50 ml
250 ml
500 ml

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 28 days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once opened use by: _____.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label – 50 ml, 250 ml & 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcimec 10 mg/ml solution for injection [IE]
Porcimec P 10 mg/ml solution for injection [BE]

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10 mg/ml

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 28 days

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Once opened use by: _____.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcimec 10 mg/ml solution for injection for pigs [IE]
Porcimec P 10 mg/ml solution for injection for pigs [BE]

2. Composition

Each ml contains

Active substance:
Ivermectin 10 mg

A clear colourless solution.

3. Target species

Pigs.

4. Indications for use

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful parasites of pigs:

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

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use by intramuscular or intravenous administration.
Do not use in cats and dogs as severe adverse reactions may occur.

6. Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary

medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal or herd.

Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test (FECRT)).

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authority.

Special precautions for safe use in the target species:
The veterinary medicinal product has been formulated specifically for use in pigs only. It should not be administered to other species as severe adverse reactions may occur. 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Take care to avoid self-administration: the veterinary medicinal product may cause local irritation and/or pain at the site of injection.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:
See the ‘Special precautions for disposal’ section of this package leaflet.

Pregnancy:
Do not administer the veterinary medicinal product during the first 40 days of pregnancy.

Fertility:
The veterinary medicinal product can be used in breeding sows and boars and will not affect fertility.

Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal product can be used concurrently without adverse effects with foot and mouth disease vaccine or clostridial vaccine, given at separate injection sites.

Overdose:
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 recumbency.

Major incompatibilities:
None known.

7. Adverse events

Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site pain*

*Mild and transient discomfort has been observed in pigs following subcutaneous injection at the injection site. All these reactions disappeared without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs. 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 hypodermic syringe, use a separate sterile needle to withdraw the veterinary medicinal product from the container.

In pigs, the recommended dosage level is 300 mcg ivermectin per kg bodyweight. This is equivalent to 1 ml per 33 kg bodyweight. The recommended route of administration is by subcutaneous injection into the neck.

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

9. Advice on correct administration

It is important that the correct dose is given in order to minimise the risk of resistance. Assess bodyweight as accurately as possible before calculating the dosage.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogenous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Accuracy of the dosing device should be thoroughly checked.

10. Withdrawal periods

Meat and offal: 28 days

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Cardboard box with 1 x 50 ml bottle
Cardboard box with 1 x 250 ml bottle
Cardboard box with 1 x 500 ml bottle

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

17. Other information

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic endectocides.