[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Ivermectin 10.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propylene glycol (E 1520)	613.6 mg
Glycerol formal	

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1. Target species

Cattle and pigs.

3.2. Indications for use for each target species

Treatment of infections with the following parasites in beef and non-lactating dairy cattle or pigs:

Cattle:

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*)

The veterinary medicinal product injection helps in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur.

Pigs:

Gastrointestinal Roundworms
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransom (adults)

Lungworms
Metastrongylus spp. (adults)

Lice
Haematopinus suis

Mange Mites
Sarcoptes scabiei var. *suis*

3.3. Contraindications

Do not use in cats and dogs as severe adverse reactions may occur.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer by intramuscular or intravenous route.
See section 3.5

3.4. Special warnings

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 veterinary medicinal product, or lack of calibration of the dosing device (if any).

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 *Cooperia spp.* and in *Ostertagia ostertagi* in cattle. Resistance has also been reported in *Haemonchus contortus* in cattle outside the EU. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

3.5. Special precautions for use

Special precautions for safe use in the target species:

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

The veterinary medicinal 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.

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).

In addition, care should be taken to avoid ingestion of spilled veterinary medicinal product or access to used containers by these other species.
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

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

The veterinary medicinal product may cause local irritation and/or pain at the site of injection. Direct contact of the veterinary medicinal product with the skin should be avoided. Take care to avoid self-administration.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

This veterinary medicinal product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore, repeated treatments on a pasture within a season should only be given on the advice of a veterinarian.

3.6. Adverse events

Cattle and pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site pain[2]

[1] Transient. These reactions can last up to 2 days and disappear without treatment.
[2] Transient.

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

Fertility:

In pigs, the veterinary medicinal product can be used in breeding sows and boars.
The fertility of males is not affected by administration of the veterinary medicinal product.

3.8. Interaction with other medicinal products and other forms of interaction

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.

3.9. Administration routes and dosage

Single subcutaneous use.

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.
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 overdosing.

Cattle:
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.

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

Pigs:
At the recommended dosage level of 300 µg ivermectin per kg of bodyweight, administer only subcutaneously in the neck in pigs.

Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs.

Use the following dosage table:

Weight (kg)	Dose (ml)
8	0.25
8 – 16	0.5
17 – 33	1.0
34 - 50	1.5
51 – 66	2.0
67 – 99	3.0
100 – 133	4.0
134 – 166	5.0
167 - 200	6.0

Over 200 kg bodyweight, give 1.0 ml per 33 kg bodyweight.

The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 1.4 x 15 mm (17-gauge x 1/2 inch) needle is suggested. Injection of wet or dirty animals is not recommended.
Vial stoppers must not be broached more than 20 times.
In young pigs, especially those weighing under 16kg for which less than 0.5ml of the veterinary medicinal product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver increments of 0.1ml is recommended. For piglets weighing less than 16kg give 0.1ml/3kg.

When treating pigs of less than 16kg seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml.

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

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

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 recumbency.

If overdose occurs, apply symptomatic treatment.

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

3.12. Withdrawal period

Cattle:

Meat and offal: 49 days.

Milk: 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.

Pigs:

Meat and offal: 28 days

4. PHARMACOLOGICAL INFORMATION

4.1. ATCVet code:

QP54AA01

4.2. Pharmacodynamics

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

4.3. Pharmacokinetics

After subcutaneous administration of the recommended dose of ivermectin to cattle (0,2 mg Ivermectin / kg), the following parameters were observed: C_{max} of 44 ng/ml (range: 25.6 – 72.5), t_{max} of 88 h, and AUC of 9702 ng·h/ml. It is also established that Ivermectin is highly bound to plasma proteins (80 %).
Due to its high lipophilic nature, ivermectin is extensively distributed. It tends to accumulate in fat tissue, which acts as a drug reservoir and the highest levels of ivermectin are found in liver and fat.

Ivermectin undergoes little metabolism; most of the dose is excreted unchanged. In cattle, only about 1-2 % is excreted in urine; the remainder is excreted in faeces, approximately 60% is excreted as unaltered drug. The remainder is excreted as metabolites. Non-polar metabolites are found in fat. Ivermectin is also excreted by the mammary gland.

In pigs, after subcutaneous administration of the recommended dose of the veterinary medicinal product to pig (0,3 mg Ivermectin / kg), a maximum plasmatic concentration of 10 – 20 ng/ml in approximately 2 days is reached.
It is mainly eliminated in faeces and urine. Maximum residues are found in liver and fat, as main product with minor polar metabolites.

5. PHARMACEUTICAL PARTICULARS

5.1. Major incompatibilities

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

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

Keep the vials in the outer carton.

5.4. Nature and composition of immediate packaging

Polypropylene vials provided with stoppers of bromobutyl type I and metallic aluminium capsules with flip-off ring

Pack sizes:
Box with 1 vial of 50 ml
Box with 1 vial of 100 ml
Box with 1 vial of 500 ml
Box with 6 vials of 50 ml
Box with 10 vials of 50 ml
Box with 12 vials of 50 ml
Box with 6 vials of 100 ml
Box with 10 vials of 100 ml
Box with 12 vials of 100 ml
Box with 6 vials of 500 ml
Box with 10 vials of 500 ml
Box with 12 vials of 50 0ml

Not all pack sizes may be marketed.

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

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

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

Do not contaminate surface waters or ditches with the veterinary medicinal product or used containers.

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

LABORATORIOS CALIER, S.A.

7. MARKETING AUTHORISATION NUMBER (S)

8. DATE OF THE FIRST AUTHORISATION

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

10. CLASSIFICATION OF THE 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

Cardboard box 50, 100, 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10.0 mg/ml

3. PACKAGE SIZE

50 ml
100 ml
500 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle: Meat and offal: 49 days.
Milk: 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.
Pigs: Meat and offal: 28 days

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vials in the outer carton.

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

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml solution for injection for cattle and pigs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ivermectin 10.0 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 28 days. Use by…

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 100 and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTIN 10 mg/ml solution for injection for cattle and pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 10.0 mg/ml

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle: Meat and offal: 49 days.
Milk: 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.
Pigs: Meat and offal: 28 days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days. Use by…

7. SPECIAL STORAGE PRECAUTIONS

Keep the vials in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

IVERTIN 10 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:

Active substance:
Ivermectin 10.0 mg

Excipients:
Propylene glycol (E 1520) 613.6 mg

Clear, colourless solution.

3. Target species

Cattle and pigs

4. Indications for use

Treatment of infections with the following parasites in beef and non-lactating dairy cattle or pigs:

Cattle:

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*)

The veterinary medicinal product injection helps in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur.

Pigs:

Gastrointestinal Roundworms
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum spp.
Strongyloides ransom (adults)

Lungworms
Metastrongylus spp. (adults)

Lice
Haematopinus suis

Mange Mites
Sarcoptes scabiei var. *suis*

5. Contraindications

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

6. Special warnings

Special warnings:

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 veterinary medicinal product, or lack of calibration of the dosing device (if any).

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 *Cooperia spp.* and in *Ostertagia ostertagi* in cattle. Resistance has also been reported in *Haemonchus contortus* in cattle outside the EU. Therefore, the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of this helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for safe use in the target species:

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

The veterinary medicinal 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.

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).

In addition, care should be taken to avoid ingestion of spilled veterinary medicinal product or access to used containers by these other species.
Since ivermectin is highly bound to plasma proteins, special care should be taken in cases of sick animals or in nutritional conditions associated with low plasma protein levels.

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

The veterinary medicinal product may cause local irritation and/or pain at the site of injection.
Direct contact of the veterinary medicinal product with the skin should be avoided. Take care to avoid self-administration.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

The veterinary medicinal product is very toxic to aquatic organisms and dung insects. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore, repeated treatments on a pasture within a season should only be given on the advice of a veterinarian.

Fertility:

In pigs, the veterinary medicinal product can be used in breeding sows and boars.
The fertility of males is not affected by administration of the veterinary medicinal product.

Interaction with other medicinal products and other forms of interaction:

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.

Overdose:

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

If overdose occurs, apply symptomatic treatment.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle and pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site pain[2]

[1] Transient. These reactions can last up to 2 days and disappear without treatment.
[2] Transient.

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 its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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

Single subcutaneous use.

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.
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 overdosing.

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

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

Pigs
At the recommended dosage level of 300 µg ivermectin per kg of bodyweight, administer only subcutaneously in the neck in pigs.

Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs.

Use the following dosage table:

Weight (kg)	Dose (ml)
8	0.25
8 – 16	0.5
17 – 33	1.0
34 - 50	1.5
51 – 66	2.0
67 – 99	3.0
100 – 133	4.0
134 – 166	5.0

167 - 200	6.0

Over 200 kg bodyweight, give 1.0 ml per 33 kg bodyweight.

9. Advice on correct administration

Cattle
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.

Pigs
The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 1.4 x 15 mm (17-gauge x 1/2 inch) needle is suggested. Injection of wet or dirty animals is not recommended.
Vial stoppers must not be broached more than 20 times.
In young pigs, especially those weighing under 16kg for which less than 0.5ml of the veterinary medicinal product is indicated, dosing accuracy is important. The use of a syringe that can accurately deliver increments of 0.1ml is recommended. For piglets weighing less than 16kg give 0.1ml/3kg.

When treating pigs of less than 16kg seek veterinary advice regarding the use of 1ml disposable syringes graduated in increments of 0.1ml.

10. Withdrawal periods

Cattle: Meat and offal: 49 days.
Milk: 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.
Pigs: Meat and offal: 28 days

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vials in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. 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

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

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

Do not contaminate surface waters or ditches with the veterinary medicinal product or used containers.

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. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Pack sizes:
Box with 1 vial of 50 ml
Box with 1 vial of 100 ml
Box with 1 vial of 500 ml
Box with 6 vials of 50 ml
Box with 10 vials of 50 ml
Box with 12 vials of 50 ml
Box with 6 vials of 100 ml
Box with 10 vials of 100 ml
Box with 12 vials of 100 ml
Box with 6 vials of 500 ml
Box with 10 vials of 500 ml
Box with 12 vials of 50 0ml

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla del Ramassà)
LES FRANQUESES DEL VALLÈS, (Barcelona)

SPAIN

Local representatives and contact details to report suspected adverse events: