[Version 9, 03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTOTAL 10 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ivermectin……10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	10 mg
Ethanol (96 per cent)	
Water for injections	
Propylene glycol	

A clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep and pigs.

3.2 Indications for use for each 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 phlebotomum
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 the product 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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer by the intravenous or intramuscular route.

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 bodyweight, misadministration of the 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.

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.

Resistance to ivermectin has been reported in *Ostertagia circumcinta in* lambs and in *Ostertagia ostertagi, Cooperia oncophora* 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Swab septum before removing each dose.

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

Handle the veterinary medicinal product with care to avoid accidental self-injection, which may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.
People with known hypersensitivity to ivermectin or benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid direct contact with skin or eyes. In case of accidental spillage onto skin or eyes, wash immediately with plenty of water.
Do not eat, drink or smoke while handling the veterinary medicinal product.
Wash your hands after using the veterinary medicine.

Special precautions for the protection of the environment:

Ivermectin is very toxic to aquatic organisms and to coprophilous insects. Treated animals should not have direct access to ponds, streams or ditches for 14 days after treatment. Long-term effects on coprophilous insects caused by continuous or repeated use cannot be excluded. Therefore, repeated treatments on a pasture in the same season should only be administered on the advice of a veterinarian.

3.6 Adverse events

Sheep and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort Injection site swelling, injection site thickening[1].

[1] Typically these reactions are transient and disappear within one to four weeks.

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort Injection site swelling, injection site thickening[1] Behavioural disorder [2].

[1] Typically these reactions are transient and disappear within one to four weeks.
[2] It may include jumping and rolling. Behaviour returns to normal after 15 minutes.

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation. In cows and sheep producing milk for human consumption see section 3.12.

Fertility:

Fertility of males is not adversely affected after treatment.

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 (see section 3.5).

3.9 Administration routes and dosage

For single administration only (except for the treatment of *Psoroptes ovis* infections in sheep).

To ensure administration of a correct dose, bodyweight 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.

Cattle

Dosage:
0.2 mg ivermectin per kg bodyweight, is equivalent to 1.0 ml/50 kg bodyweight.

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

Sheep

Dosage:
0.2 mg ivermectin per kg bodyweight, is equivalent to 0.5 ml/25 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 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:

0.3 mg ivermectin per kg bodyweight, is equivalent to 1.5 ml/50 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 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.

When using the 250 or 500 ml pack sizes, use only automatic syringe equipment. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper. The stopper may be safely punctured up to 30 times.

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

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.

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

ES: Administration by a veterinarian surgeon or under their close supervision.

3.12 Withdrawal periods

Cattle:

Meat and offal: 49 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Sheep:

Meat and offal: 42 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Pigs:

Meat and offal: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a mixture of two partially modified compounds of abamectin that belongs to the family of avermectins, which are a class of macrocyclic lactones from the group of endectocides. Abamectin is a mixture of two fermentation products of the soil organism *Streptomyces avermitilis*.
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.

4.3 Pharmacokinetics

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, T1/2 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, T1/2 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, T1/2 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%).

Environmental properties

Ivermectin has adverse effects on the environment. After treatment, toxic levels of ivermectin are excreted for weeks. Faeces excreted on the grass by treated animals reduces the abundance of coprophagous organisms which could affect the degradation of feces.
Ivermectin is very toxic to aquatic organisms and the coprophagous fauna and can accumulate in soil and sediment.

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: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3. Special precautions for storage

Store below 30 °C.

5.4 Nature and composition of immediate packaging

Translucent polypropylene cylindrical vials (Eur. Ph.) with grey butyl rubber cap, grey aluminum capsule and Flip-Off seal.

Pack sizes:
- Box with 1 vial of 250 ml
- Box with 1 vial of 500 ml
- Box with 10 vials of 250 ml
- Box with 10 vials of 500 ml

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

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

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

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

ES: 2937 ESP
PT: 1207/01/18RFVPT

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 12/12/2013

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

Box for 250 ml and 500 ml
Box with 10 vials of 250 ml or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTOTAL 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ivermectin……10 mg

3. PACKAGE SIZE

250 ml
500 ml

4. TARGET SPECIES

Cattle, sheep and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal: 49 days.
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Sheep:

Meat and offal: 42 days.
Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Pigs:

Meat and offal: 28 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by 28 days.
Once broached use by…...

9. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

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

S.P. VETERINARIA, S.A.

14. MARKETING AUTHORISATION NUMBERS

ES: 2937 ESP
PT: 1207/01/18RFVPT

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE INMEDIATE PACKAGE

Vials of 250 ml and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTOTAL 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ivermectin……10 mg

3. TARGET SPECIES

Cattle, sheep and pigs.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:

Meat and offal: 49 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Sheep:

Meat and offal: 42 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Pigs:

Meat and offal: 28 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by 28 days.
Once broached use by…...

7. SPECIAL STORAGE PRECAUTIONS

Store below 30 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

IVERTOTAL 10 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance:
Ivermectin.....10 mg

Excipients:
Benzyl alcohol (E 1519).....10 mg

A clear, colourless solution.

3. Target species

Cattle, sheep and pigs.

4. Indications for use

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 phlebotomum
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 the product 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

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer by the intravenous or intramuscular 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 bodyweight, misadministration of the 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.

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.

Resistance to ivermectin has been reported in *Ostertagia circumcinta in* lambs and in *Ostertagia ostertagi, Cooperia oncophora* 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.

Special precautions for safe use in the target species:
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.

Swab septum before removing each dose.

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

Handle the veterinary medicinal product with care to avoid accidental self-injection, which may cause local irritation and/or pain at the injection site. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.
People with known hypersensitivity to ivermectin or benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid direct contact with skin or eyes. In case of accidental spillage onto skin or eyes, wash immediately with plenty of water.
Do not eat, drink or smoke while handling the veterinary medicinal product.
Wash your hands after using the veterinary medicine.

Special precautions for the protection of the environment:
Ivermectin is very toxic to aquatic organisms and to coprophilous insects. Treated animals should not have direct access to ponds, streams or ditches for 14 days after treatment. Long-term effects on coprophilous insects caused by continuous or repeated use cannot be excluded. Therefore, repeated treatments on a pasture in the same season should only be administered on the advice of a veterinarian.

Pregnancy and lactation:
Can be used during pregnancy and lactation. In cows and sheep producing milk for human consumption see section 10.

Fertility:
Fertility of males is not adversely affected after treatment.

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 (see section Special precautions for use).

Overdose:
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.

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

7. Adverse events

Sheep and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort Injection site swelling, injection site thickening[1].

[1] Typically these reactions are transient and disappear within one to four weeks.

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Discomfort Injection site swelling, injection site thickening[1] Behavioural disorder [2].

[1] Typically these reactions are transient and disappear within one to four weeks.
[2] It may include jumping and rolling. Behaviour returns to normal after 15 minutes.

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: {national system details}

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

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

To ensure administration of a correct dose, bodyweight 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.

Cattle

Dosage:
0.2 mg ivermectin per kg bodyweight, is equivalent to 1.0 ml/50 kg bodyweight

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

Sheep

Dosage:
0.2 mg ivermectin per kg bodyweight, is equivalent to 0.5 ml/25 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 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:

0.3 mg ivermectin per kg bodyweight, is equivalent to 1.5 ml/50 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 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.

9. Advice on correct administration

When using the 250 or 500 ml pack sizes, use only automatic syringe equipment. To refill the syringe, use of a draw-off needle is recommended to avoid excessive broaching of the stopper. The stopper may be safely punctured up to 30 times.

10. Withdrawal periods

Cattle:

Meat and offal: 49 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Sheep:

Meat and offal: 42 days.

Milk: Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals which are intended to produce milk for human consumption within 60 days of expected parturition.

Pigs:

Meat and offal: 28 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the 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 may be dangerous for fish and other aquatic organisms.

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.
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

ES: 2937 ESP

PT: 1207/01/18RFVPT

Pack sizes:

- Box with 1 vial of 250 ml
- Box with 1 vial of 500 ml
- Box with 10 vials of 250 ml
- Box with 10 vials of 500 ml

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:
S.P. VETERINARIA, S.A.
Ctra. Reus-Vinyols, km 4,1
43330 Riudoms (ESPAÑA)

Manufacturer responsible for batch release:
CENAVISA, S.L.
Cami Pedra Estela s/n
43205 Reus
Tarragona (España)

ES: Local representatives and contact details to report suspected adverse reactions:
S.P. VETERINARIA, S.A.
Ctra. Reus-Vinyols, km 4,1
43330 Riudoms (ESPAÑA)
Tel. +34 977 850 170
pharmacovigilance@spveterinaria.com

PT: Local representatives and contact details to report suspected adverse reactions:
REPRESENTAGRO – REPRESENTAÇOES LDA
Estrada da Lapa 1,
PT- 2665-540 Venda do Pinheiro
Tel: + 00351 219 662 744
geral@representagro.pt

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Ivermectin has adverse effects on the environment. After treatment, toxic levels of ivermectin are excreted for weeks. Faeces excreted on the grass by treated animals reduces the abundance of coprophagous organisms which could affect the degradation of feces.

Ivermectin is very toxic to aquatic organisms and the coprophagous fauna and can accumulate in soil and sediment.