[Version 8.1,01/2017]

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Vial 500 ml and 250 ml
Box 500 ml and 250 ml
Label 10x250 ml and 10 x 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTOTAL 10 mg/ml solution for injection
Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Ivermectin……10 mg

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution

4. PACKAGE SIZE

250 ml
500 ml

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle:

Meat and offal: 49 days.
Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers, within 60 days of calving.

Sheep:

Meat and offal: 42 days.
Do not use in lactating ewes producing milk for human consumption. Do not use in sheep which are intended to produce milk for human consumption within 60 days of lambing.

Pigs:

Meat and offal: 28 days

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Store below 30 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

BOX: Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

BOX: Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

SP VETERINARIA, S.A.
Ctra. Reus – Vinyols Km 4,1 43330
Riudoms (Tarragona)
SPAIN

16. MARKETING AUTHORISATION NUMBER

BOX: ES: 2937 ESP

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
IVERTOTAL 10 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

SP VETERINARIA, S.A.
Ctra. Reus – Vinyols Km 4,1 43330
Riudoms (Tarragona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

IVERTOTAL 10 mg/ml solution for injection
Ivermectin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Ivermectin……10 mg

Excipients:
Benzyl alcohol (E 1519)…….10 mg
Other excipients, q.s.

4. INDICATIONS

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 lactating dairy cows and sheep producing milk for human consumption.
Do not use in non-lactating dairy cows, including pregnant dairy heifers or non-lactating dairy sheep within 60 days of calving/lambing.
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. ADVERSE REACTIONS

Transitory discomfort has been observed in some animals immediately following subcutaneous administration. In cattle this may include jumping and rolling, but behaviour returns to normal after 15 minutes.
Soft tissue swelling and thickening of the skin at the injection site has been observed in treated animals. Typically these reactions are transient and disappear within one to four weeks.

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 inform your veterinary surgeon.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, sheep and pigs.

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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIODS

Cattle:

Meat and offal: 49 days.

Do not use in lactating cows producing milk for human consumption. Do not use in non-lactating dairy cows, including pregnant dairy heifers, within 60 days of calving.

Sheep:

Meat and offal: 42 days.

Do not use in lactating ewes producing milk for human consumption. Do not use in sheep which are intended to produce milk for human consumption within 60 days of lambing.

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 WARNINGS

Special warnings for each target species:
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time
- Underdosing, which may be due to underestimation of 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 use in animals:
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:
Do not smoke, eat or drink while handling the product.
Wash hands after use.
Take care to avoid self injection: the product may cause local irritation and/or pain at the site of injection.

Other precautions:
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/Lactation:
The product can be administered during pregnancy in cows, ewes and sows (for information on use in lactating animals, see sections Contraindications and Withdrawal periods.
The fertility of males is not affected by administration of the 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 (see section Special precautions for use).

Overdose (symptoms, emergency procedures, 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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Treated animals should not have access to surface waters for 14 days after treatment to avoid effects on aquatic organisms. Do not contaminate surface waters or ditches with product or used container. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.