ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 200, 500 or 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivermectin and Clorsulon 10 mg/ml / 100 mg/ml solution for injection Virbac

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances:

Ivermectin	10	mg/ml
Clorsulon	100	mg/ml

3. PACKAGE SIZE

200 ml
500 ml
1000 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Meat and offal: 66 days.
Milk:
Not authorised for use in animals producing milk for human consumption.

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.
Protect from light.

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 reach and sight of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/3028

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivermectin and Clorsulon 10 mg/ml / 100 mg/ml solution for injection Virbac

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin	10	mg/ml
Clorsulon	100	mg/ml

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 66 days.
Milk:
Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

Store in the original container.
Protect from light.
Following withdrawal of the first dose, use the product within 28 days

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial of 500 and 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivermectin and Clorsulon 10 mg/ml / 100 mg/ml solution for injection Virbac

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin	10	mg/ml
Clorsulon	100	mg/ml

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 66 days.
Milk:
Not authorised for use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

Protect from light.
Store in the original container.
Following withdrawal of the first dose, use the product within 28 days.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ivermectin and Clorsulon 10 mg/ml / 100 mg/ml solution for injection Virbac

2. Composition

Each ml contains :

Active substances:
Ivermectin ..... 10 mg
Clorsulon ..... 100 mg

Excipient:
Propyl gallate (E310)……. 0.2 mg

Clear, slightly yellow and slightly viscous solution.

3. Target species

Cattle.

4. Indications for use

For the treatment of mixed trematode and nematode or arthropod infestations, due to adult and immature roundworms, lungworms, warbles, mites, lice and liver fluke in cattle.

Gastro-intestinal roundworms (adult and fourth-stage larvae):

Ostertagia ostertagi (including inhibited larval stages)
O. lyrata
Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis
Cooperia oncophora
Cooperia punctata
Cooperia pectinata
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
Nematodirus spathiger (adult)

Lungworms (adult and fourth-stage larvae):

Dictyocaulus viviparus

Liver fluke (adult):

Fasciola hepatica

Warbles (parasitic stages):
Hypoderma bovis
Hypoderma lineatum

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

Sucking lice:
Linognathus vituli
Haematopinus eurysternus

The product may also be used as an aid in the control of the mange mite *Chorioptes bovis*, but complete elimination may not occur.

5. Contraindications

Do not use in cattle producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.
Not for use in species other than cattle as severe adverse reactions, including fatalities, may occur in dogs for example.
Do not use by the intravenous or intramuscular route.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

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 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.

Special precautions for safe use in the target species:

Divide doses greater than 10 ml between two injection sites to reduce occasional discomfort or site reaction.
Frequent and repeated use may lead to the development of resistance.
The timing of treatment for the parasitic stages of warbles should be chosen carefully. The best time to treat against infections with *Hypoderma* is immediately after the end of the swarming of the warbles, before the larvae cause damage in the body of the animal (October to November). If larvae of *Hypoderma bovis* are killed during migration through the spine, this may induce posterior paralysis and recumbency. These reactions occur mainly when animals are treated between December and March.

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

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

Other precautions:

Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

Pregnancy and lactation:

Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

Interactions with other medicinal products and other forms of interaction:

The effects of GABA agonists are increased by ivermectin.

Overdose:

An acute toxic syndrome consisting of CNS signs of depression and listlessness, ataxia, recumbency and possible death occurs in cattle given S.C. doses equal to 40 times the therapeutic dose for ivermectin. Treatment should be symptomatic.
A toxic-syndrome dose level has not been identified in cattle for clorsulon.

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

Undetermined frequency (cannot be estimated from the available data)
Discomfort[1] Injection site swelling[2], Injection site pain[2,3] Hypersensitivity reaction[4]

[1]Transitory.
[2]Soft-tissue reactions, disappeared without treatment.
[3]Slight.
[4]Symptomatic treatment should be applied.

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

The product should be given once by subcutaneous injection at the recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kilogram of bodyweight. Each ml contains 10 mg of ivermectin and 100 mg of clorsulon, sufficient to treat 50 kg of bodyweight. Subcutaneous injection only.

9. Advice on correct administration

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

Divide doses greater than 10 ml between two injection sites.
Inject under the loose skin behind the shoulder. Use of a 17 gauge, ½ inch (15-20 mm) needle is suggested. The injection may be given with any standard automatic, multidose or single-dose hypodermic syringe. If using a hypodermic syringe, use a separate sterile needle to withdraw the dose from the pack.

This product does not contain an antimicrobial preservative. Swab septum before removing each dose. Use a dry, sterile needle and syringe.
For 200, 500 and 1000 ml pack sizes, use only automatic syringe equipment.
Injection on animals with wet or dirty hides is not recommended.

When the temperature of the product is below 5°C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection

equipment to about 15°C will greatly increase the ease with which the product can be injected. Different injection sites should be used for other parenteral products.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon.

10. Withdrawal periods

Meat and offal : 66 days.
Milk:
Not authorised for use in animals producing milk for human consumption.
Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

11. Special storage precautions

Keep out of the reach and sight of children.

Store in the original container.
Protect from light.
Shelf life after first opening the immediate packaging: 28 days.

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

12. Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as ivermectin and clorsulon is extremely dangerous to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

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 the veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 05653/3028

Vials of 200 ml, 500 ml and 1000 ml.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representative(s) and contact details to report suspected adverse reactions:

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

Gavin Hall
Approved: 10 July 2024