# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Box of 200, 500 or 1000 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUPREMADEX 10 mg/ml / 100 mg/ml Solution for Injection
Ivermectin/Clorsulon

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

Excipient:
Propyl gallate (E310)

## 3. PHARMACEUTICAL FORM

Solution for injection.

## 4. PACKAGE SIZE

200 ml
500 ml
1000 ml

## 5. TARGET SPECIES

Cattle.

## 6. INDICATION(S)

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.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Each ml contains 10 mg of ivermectin and 100 mg of clorsulon, sufficient to treat 50 kg of bodyweight. Subcutaneous injection only.

## 8. WITHDRAWAL PERIOD

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

## 9. SPECIAL WARNING(S), IF NECESSARY

None.

## 10. EXPIRY DATE

EXP : {month/year}

## 11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
ère avenue 2065m LID
06516 Carros
France

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5059

## 17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

**Vial of 200 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUPREMADEX 10 mg/ml / 100 mg/ml Solution for Injection
Ivermectin/Clorsulon

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Solution for injection.

## 4. PACKAGE SIZE

200 ml

## 5. TARGET SPECIES

Cattle.

## 6. INDICATION(S)

Read the package leaflet before use.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Meat and offal : 66 days. Milk: Do not use in animals producing milk for human consumption. Read the package leaflet before use.

## 9. SPECIAL WARNING(S), IF NECESSARY

None.

## 10. EXPIRY DATE

EXP : {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Protect from light.
Read the package leaflet before use.

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

Read the package leaflet before use.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5059

## 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**

**Vial of 500 and 1000 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUPREMADEX 10 mg/ml / 100 mg/ml Solution for Injection
Ivermectin/Clorsulon

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Solution for injection.

## 4. PACKAGE SIZE

500 ml
1000 ml

## 5. TARGET SPECIES

Cattle.

## 6. INDICATION(S)

Read the package leaflet before use.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

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

## 9. SPECIAL WARNING(S), IF NECESSARY

None.

## 10. EXPIRY DATE

EXP: {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

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

Read the package leaflet before use.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5059

## 17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## SUPREMADEX 10 mg/ml / 100 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:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer for the batch release: VIRBAC S.A.
1ère avenue – 2065 m –
L.I.D. 06516 Carros
France

or:

Sofarimex Indústria Química e Farmacêutica Lda
Avenida das Indústrias - Alto do Colaride - Agualva – 2735-213
Cacém Portugal

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SUPREMADEX 10 mg/ml / 100 mg/ml Solution for Injection
Ivermectin/Clorsulon

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

**Active substances:**

| | | |
|---|---|---|
| Ivermectin ..... | 10 | mg/ml |
| Clorsulon ..... | 100 | mg/ml |

**EXCIPIENT(S):**

| | | |
|---|---|---|
| Propyl gallate (E310) ……. | 0.2 | mg/ml |

## 4. INDICATION(S)

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 animals known to be hypersensitive to the active substance.

## 6. ADVERSE REACTIONS

Transitory discomfort has been observed in some cattle following subcutaneous administration. Soft-tissue swelling and/or slight pain at the injection site has also been observed. These reactions have disappeared without treatment.
In case of hypersensitivity reactions a symptomatic treatment should be applied.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD

Meat and offal: 66 days. Milk: Do not 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. Protect from light.
Store in the original container.
Following withdrawal of the first dose, use the product within 28 days.
Do not use after the expiry date which is stated on the label and carton after "EXP". When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

## 12. SPECIAL WARNING(S)

### 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 USE IN ANIMALS

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.
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.

**SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT TO ANIMALS**

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.

**USE DURING PREGNANCY, LACTATION OR LAY**

Do not use in animals producing milk for human consumption.

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

**INTERACTIONS**

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.

**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

Any unused product or waste material should be disposed of in accordance with national requirements.
EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or empty container.

## 14. 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.

## 15. OTHER INFORMATION

Pack sizes:
Vials of 200 ml, 500 ml and 1000 ml. Not all pack sizes may be marketed.

*Gavin Hall*

Approved: 10 July 2024