PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of the vials of 200 ml, 500 ml and 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec Super 10 mg/ml, 100 mg/ml Solution for Injection Ivermectin and 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
500 ml
1000 ml

5. TARGET SPECIES

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.
Read package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous route only.
The product should be given once by subcutaneous injection at the recommended dosage level of 200 µg of ivermectin and 2 mg of 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.

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 overdosing.
Divide doses greater than 10 ml between two injection sites.
Inject under the loose skin behind the shoulder. Use of a 17-gauge,
1/2-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 product 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.
To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.
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.

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

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

UNDESIRABLE EFFECTS
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.

USER WARNINGS
Do not smoke, drink or eat whilst 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. In case of accidental self-injection, seek medical advice and show the label to the doctor.

SPECIAL WARNINGS
Care should be taken to avoid the following practices because they increase the risk of the development of resistance and could ultimately result in ineffective therapy.

OTHER PRECAUTIONS
Ivermectin is highly toxic to aquatic invertebrates. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment to avoid adverse effects on aquatic organisms.

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.

SPECIAL PRECAUTIONS FOR USE
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.

OVERDOSE
An acute toxic syndrome consisting of CNS signs of depression and listlessness, ataxia, recumbency and possible death occurs in cattle given SQ 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.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 28 days Once broached use by:……

11. SPECIAL STORAGE CONDITIONS

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded.
Protect from light.
Store in the original container.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
EXTREMELY DANGEROUS to fish and aquatic life.
Do not contaminate ponds, waterways or ditches with the product or empty container.

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

[Distribution category]

FOR ANIMAL TREATMENT ONLY
To be supplied only on veterinary prescription POM-VPS

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

KEEP OUT OF THE SIGHT AND REACH 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 05653/4155

17. MANUFACTURER'S BATCH NUMBER

Lot: number

Distributor: VIRBAC Ltd Suffolk IP30 9UP – UK

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of vials of 200 ml, 500 ml and 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec Super 10 mg/ml, 100 mg/ml, solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active
substances:
ivermectin 10
mg/ml
clorsulon 100
mg/ml Excipient:
propyl gallate (E310) 0.2 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

200 ml
500 ml
1000 ml

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.
Read package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Inject once subcutaneously, at the dosage of 1 ml per 50 kg of bodyweight. Read 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

CONTRA-INDICATIONS, UNDESIRABLE EFFECTS, SPECIAL PRECAUTIONS FOR USE, USE DURING PREGNANCY AND LACTATION, OVERDOSE, USER WARNINGS
Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the immediate packaging: 28 days Once broached use by: …….....

11. SPECIAL STORAGE CONDITIONS

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded. Protect from light. Store in the original container.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
EXTREMELY DANGEROUS to fish and aquatic life.
Do not contaminate ponds, waterways or ditches with the product or empty container.

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

[Distribution category]

FOR ANIMAL TREATMENT ONLY.
To be supplied only on veterinary prescription. POM-VPS

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

KEEP OUT OF THE SIGHT AND REACH 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 05653/4155

17. MANUFACTURER'S BATCH NUMBER

Lot: number

Distributor: VIRBAC Ltd Suffolk IP30 9UP – UK

PACKAGE LEAFLET
FOR:

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:
VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec Super 10 mg/ml, 100 mg/ml Solution for Injection

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

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

Other substance
Propyl gallate (E310)…… 0.2mg/ml

Clear, slightly yellow and slightly viscous solution

4. INDICATIONS

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) *Ostertagia 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. CONTRA-INDICATIONS

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

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 µg of ivermectin and 2 mg of 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.

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.

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.

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.

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

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded.
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 carton should be discarded should be worked out. This discard date should be written in the space provided.

Protect from light.
Store in the original container.

Do not use this veterinary medicinal product after the expiry date stated on the carton and vial 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

WARNING(S) USER

WARNINGS
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. In case of accidental self-injection, seek medical advice and show the label to the doctor.

SPECIAL PRECAUTIONS FOR USE
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.

OTHER PRECAUTIONS
Ivermectin is highly toxic to aquatic invertebrates. Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment to avoid adverse effects on aquatic organisms.

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.

OVERDOSE
An acute toxic syndrome consisting of CNS signs of depression and listlessness, ataxia, recumbency and possible death occurs in cattle given SQ 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.

INTERACTIONS
Not known.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local 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 PRESENTATIONS

Sizes: 200-ml, 500-ml and 1L; multidose colourless-plastic vials. Not all pack sizes may be marketed.

FOR ANIMAL TREATMENT ONLY
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

To be supplied only on veterinary prescription. Vm 05653/4155
POM-VPS

Distributor: VIRBAC Ltd - Suffolk IP30 9UP – UK

Approved 11 April 2024