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

Ivermectin Virbac 10 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCE

Active substances
Ivermectin……. 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

200 ml
500 ml
1000 ml

5. TARGET SPECIES

Cattle, swine and sheep.

6. INDICATION(S)

The product is indicated for the treatment and control of internal and external parasites.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous injection.
Please refer to the package leaflet.

8. WITHDRAWAL PERIOD

Cattle must not be treated within 49 days of slaughter for human consumption. Do not use in cattle producing milk for human consumption. Do not use in non- lactating cows including pregnant heifers within 60 days of calving.

Swine must not be treated within 28 days of slaughter for human consumption.

Sheep must not be treated within 42 days of slaughter for human consumption.

Do not use in sheep producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS
Do not use by the intravenous or intramuscular route.
Not for use in species other than cattle and swine as severe adverve reactions including fatalities in dogs may occur.
In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although a clinicial improvement may be seen, eliminator of all mites may not occur.

UNDESIRABLE EFFECTS
Studies have shown a wide safety margin and, at the recommended dosage, no adverse effect on breeding performance were observed.
At therapeutic doses, ivermectin has no adverse effect on cattle, swine or sheep since it does not readily penetrate their central nervous systems. Transitory discomfort has occasionally been observed in some cattle, pigs and sheep following subcutaneous administration. A low incidence of soft-tissue swelling at the injection site has been observed in those species. These reactions have disappeared without treatment.

OPERATOR WARNINGS
Do not smoke, drink or eat whilst handling the product. Wash hands after use. Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.

SPECIAL PRECAUTIONS FOR USE
As this product does not contain any antimicrobial preservative, swab septum before removing each dose. Use sterile needle and syringe. When using the 200-ml, 500-ml and 1000-ml pack sizes, use only automatic syringe equipment.

SPECIAL WARNINGS
Sheep scab (*Psoroptes ovis)* is an extremely-contagious external parasite of sheep. Following treatment of infected sheep, great care must be taken to avoid reinfestations, 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. Adequate vaccination of sheep against clostridial infection is strongly recommended.

USE DURING PREGNACY AND LACTATION
The product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It can be use in breeding ewes and rams and will not affect fertility.

OVERDOSAGE:
cattle : single doses of 4 mg of ivermectin per kg (20 times the use level) given subcutaneously resulted in ataxia and depression.

Swine : a dose of 30 mg of ivermectin per kg (100 times the use level) injected subcutaneously caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, labored breathing and lateral recumbency.
For these species, no antidote has been identified. However, symptomatic therapy may be beneficial.

10. EXPIRY DATE

Following withdrawal of the first dose, use the product within 6 months. Discard unused material.

11. SPECIAL STORAGE CONDITIONS

Avoid introduction of contamination. Protect from light.
Do not store above 30 °C. Keep vial in outer carton.
This product does not contain any antimicrobial preservative.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste- regulation authority.
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used 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 on veterinary prescription
POM-VPS
U.K. authorised veterinary medicinal product

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

Keep out of the reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER

Vm 05653/4203

17. MANUFACTURER'S BATCH NUMBER

Batch : number

Distributed by Virbac Ltd, Suffolk, IP30 9UP, UK

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Vials of 200 ml, 500 ml and 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivermectin Virbac 10 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCE

Active substances
Ivermectin…….. 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

200 ml
500 ml
1000 ml

5. TARGET SPECIES

Cattle, swine and sheep.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Do not use by the intravenous or intramuscular route. Not for use in species other than cattle, swine and sheep as severe adverse reactions including fatalities in dogs may occur. In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although a clinical improvement may be seen, elimination of all mites may not occur.

8. WITHDRAWAL PERIOD

Cattle must not be treated within 49 days of slaughter for human consumption. Do not use in cattle producing milk for human consumption.
Do not use in non-lactating cows including pregnant heifers within 60 days of calving. Swine must not be treated within 28 days of slaughter for human consumption.
Sheep must not be treated within 42 days of slaughter for human consumption.
Do not use in sheep producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

SPECIAL PRECAUTIONS FOR USE
To be given subcutaneously only. As this product does not contain any antimicrobial preservative, swab septum before removing each dose. Use sterile needle and syringe.
Read the package leaflet carefully for further information.

OPERATOR WARNINGS
Do not smoke, eat or drink whilst handling the product. Wash hands after use. Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.

10. EXPIRY DATE

EXP:
Following withdrawal of the first dose, use the product within 6 months. Discard unused material.
Once broached use by:

11. SPECIAL STORAGE CONDITIONS

Avoid introduction of contamination.
Do not store above 30 °C.
Protect from light.
Keep vial in outer carton.
This product does not contain any antimicrobial preservative.

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

Read package leaflet before use.

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
U.K. authorised veterinary medicinal product

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

KEEP OUT OF REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Distributed by Virbac Ltd, Suffolk, IP30 9UP, UK

16. MARKETING AUTHORISATION NUMBER

Vm 05653/4203

17. MANUFACTURER'S BATCH NUMBER

Batch: number

PACKAGE LEAFLET
FOR:

Ivermectin Virbac 10 mg/ml Solution for Injection

■ **PRESENTATION:** Ivermectin is a broad-spectrum endectocide of the avermectin family. Ivermectin is isolated after purification and hydrogenation of the
avermectin-family compounds which are obtained from the fermentation of the soil organism *Streptomyces avermitilis*. Ivermectin is a macrocyclic-lactone derivative which has a broad and potent antiparasitic activity against nematodes and arthropods. It acts by inhibiting nerve impulses. Ivermectin 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.

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivermectin Virbac 10 mg/ml Soultion for Injection

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

Active substances

Ivermectin…….. 10 mg/ml

4. INDICATION(S)

CATTLE: The product is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungoworms, eyeworms, warbles, mites and lice.

Gastro-intestinal roundworms (adult and fourth-stage larvae): *Ostertagia ostertagi* (including inhibited *O.ostertagi) Ostertagia lyrata*

Haemonchus placei
Trichostrongylus axei
Trichostrongylus colubriformis Cooperia oncophora Cooperia punctate
Cooperia pectinate
Bunostomum phlebotomum
Oesophagostomum radiatum
Strongyloides papillosus
(adult) *Nematodirus helvatianus* (adult)
Nematodirus spathiger (adult)
Trichuris spp. (adult)

Lungworms (adult and fourth-stage larvae):
Dictyocaulus viviparous

Eyeworms (adult):
Thelazia spp.

Warbles (parasitic stages): *Hypoderma bovis Hypoderma lineatum*

Mange mites:
Psoroptes bovis
Sarcoptes scabei var. bovis

Sucking lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

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

SWINE:
The product is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungworms, mites and lice.

Internal parasites

Gastro-intestinal roundworms (adult and fourth-stage larvae):
Ascaris suum
Oesophagostomum
spp. *Hyostrongylus*
rubidus
Strongyloides ransomi (adults and somatic larval stages) Lungworms:
Metastrongylus spp. (adults)

External parasites

Mites:
Sarcoptes scabei var. suis

Lice:
Haematopinus suis
The product may also be used as an aid in the control of adult whipworm (*Trichuris suis*).
Note: for effective mange control, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities.

SHEEP
The product is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungworms, nasal bots and mites.

Gastro-intestinal roundworms (adult and fourth-stage larvae):
Ostertagia circumcincta (including inhibited *O. circumcincta*)
O. trifurcata
Haemonchus contortus (including inhibited *H. contortus*) *Trichostrongylus axei* (adult)
Trichostrongylus colubriformis
Trichostrongylus vitrinus (adult)
Cooperia curticei
Oesophagostomum
columbianum
Oesophagostomum venulosum (adult)
Nematodirus
filicollis Chabertia
ovina Trichuris
ovis (adult)

Lungworms:
Dictyocaulus filaria (adult and fourth-stage larvae)
Protostrongylus rufescens (adult)

Nasal bots:
Oestrus ovis (immature stage)

Mange mites:
Psoroptes ovis (adult and immature stage)

For the treatment and control of sheep scab *Psoroptes ovis*, two injections with a seven-day interval are required to treat clinical signs of scab and to eliminate mites. Benzimidazole-resistant strains of *Haemonchus contortus* and *Ostertagia circumcincta* are also controlled.

5. CONTRAINDICATIONS

Do not use by the intravenous or intramuscular route.
Not for use in species other than cattle, swine and sheep as severe adverse reactions including fatalities in dogs may occur.
In sheep, treatment of psoroptic mange (sheep scab) with one injection is not recommended because, although a clinical improvement may be seen, elimination of all mites may not occur.

6. ADVERSE REACTIONS

Studies have shown a wide safety margin and, at the recommended dosage, no adverse effect on breeding performance were observed.
At therapeutic doses, ivermectin has no adverse effect on cattle, swine or sheep since it does not readily penetrate their central nervous systems.
Transitory discomfort has occasionally been observed in some cattle, pigs and sheep following subcutaneous administration.
A low incidence of soft-tissue swelling at the injection site has been observed in those species. These reactions have disappeared without treatment.

7. TARGET SPECIES

Cattle, swine and sheep.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The injection may be given with any standard automatic or single-dose or hypodermic syringe. Use of 17-gauge ½-inch needle is suggested. Replace with a fresh sterile needle after every 10 to 12 animals. Injection of wet or dirty animals is not recommended. If using a single-dose or hypodermic syringe, use a separate sterile needle to withdraw the product from the pack.

To ensure administration of a correct dose, body weight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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.Resistance to ivermectin (an avermectin) has been reported in Teladorsagia in sheep and goats within the EU. Resistance is common in Haemonchus in sheep outside the EU. It has been reported in Cooperia oncophora in cattle within the EU, in Teladorsagia in cattle in developed countries such as New Zealand and Haemonchus in cattle outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommandations on how to limit further selection for resistance to anthelmintics

CATTLE
The product should be given only by subcutaneous injection at the recommended dosage level of 2 mg of ivermectin per 10 kilogram of bodyweight (equivalent to 1 ml per 50 kg of bodyweight) under the loose skin in front of or behind the shoulder. Each ml contains 10 mg of ivermectin.

Dosage schedule for cattle

Bodyweight (kg)	Dose Volume (ml)
Up to 50	1.0
51 – 100	2.0
101 – 150	3.0
151 – 200	4.0
201 – 250	5.0
251 – 300	6.0
301 – 350	7.0
351 – 400	8.0
401 – 450	9.0
451 – 500	10.0
501 – 550	11.0
551 - 600	12.0

SWINE
The product should be given only by subcutaneous injection at the recommended dosage level of 3 mg of ivermectin per 10 kg of bodyweight (equivalent to 1 ml per 33 kg of bodyweight).

Dosage schedu Over 200 kg of bodyweight, give 1.0 ml per 33 kg of bodyweight.

Bodyweight (kg)	Dose Volume (ml)
Up to 16	0.5
17 – 33	1.0
34 – 50	1.5
51 – 66	2.0
67 – 99	3.0
100 – 133	4.0
134 – 166	5.0
167 - 200	6.0

Over 200 kg of bodyweight, give 1.0 ml per 33 kg of bodyweight.Inject subcutaneously in the neck in pigs.

In young pigs, especially those below 16 kg for which less than 0.5 ml of the product is indicated, dosing accurately is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.le for swine

SHEEP

To be given only by subcutaneous injection using aseptic precautions at the recommended dosage level of 200 mcg of ivermectin per kilogram of bodyweight (equivalent to 0.5 ml per 25 kg of bodyweight) in the neck.
For the treatment and control 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.

Dosage schedule for sheep

Bodyweight (kg)	Dose Volume (ml)
Up to 5	0.1
5.1 – 10	0.2
10.1 – 15	0.3
15.1 – 25	0.5
25.1 – 50	1.0
50.1 – 75	1.5
75.1 - 100	2.0

For sheep weighing over 100 kg, calculate the dose at the rate of 0.5 ml per 25 kg. When treating sheep of less than 16 kg, seek veterinary advice regarding the use of 1-ml disposable syringes graduated in increments of 0.1 ml. For the treatment of individual sheep, a syringe not exceeding 2.0 ml and calibrated in increments of 0.1 ml should be used.

9. ADVICE ON CORRECT ADMINISTRATION

General precautions
To be given by subcutaneous injection.
This product does not contain an antimicrobial preservative. Swab septum before removing each dose.

10. WITHDRAWAL PERIOD(S)

Cattle must not be treated within 49 days of slaughter for human consumption. Do not use in cattle producing milk for human consumption.
Do not use in non-lactating cows including pregnant heifers within 60 days of calving. Swine must not be treated within 28 days of slaughter for human consumption.
Sheep must not be treated within 42 days of slaughter for human consumption. Do not use in sheep producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

PHARMACEUTICAL WARNINGS
Keep out of the reach of children.
Following withdrawal of the first dose, use the product within 6 months. Discard unused material
Avoid introduction of contamination. Protect from light.
Do not store above 30 °C. Keep vial in outer carton

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.
This product does not contain any antimicrobial preservative.

12. SPECIAL WARNING(S)

OPERATOR WARNINGS
Do not smoke, eat or drink whilst handling the product. Wash hands after use.
Take care to avoid self-administration: the product may cause irritation and/or pain at the site of injection.

SPECIAL PRECAUTIONS FOR USE
As this product does not contain any antimicrobial preservative, swab septum before removing each dose. Use sterile needle and syringe. When using the 200-ml, 500-ml and 1000-ml pack sizes, use only automatic-syringe equipment.

SPECIAL WARNINGS
Sheep scab (*Psoroptes ovis*) is an extremely-contagious external parasite of sheep. Following treatment of infected sheep, great care must

be taken to avoid reinfestation, 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.

Adequate vaccination of sheep against clostridial infections is strongly recommended.

USE DURING PREGNANCY AND LACTATION
The product can be administered to ewes at any stage of pregnancy or lactation provided that the milk is not intended for human consumption. It can be used in breeding ewes and rams and will not affect fertility.

OVERDOSAGE
Cattle: single doses of 4 mg of ivermectin per kg (20 times the use level) given subcutaneously resulted in ataxia and depression. Swine: a dose of 30 mg of ivermectin per kg (100 times the use level) injected subcutaneously caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, labored breathing and lateral recumbency.
For those species, no antidote has been identified. However, symptomatic therapy may be beneficial

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste-regulation authority.
EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate ponds, waterways or ditches with the product or used 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. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. OTHER INFORMATION

PRESENTATIONS: 200 ml, 500 ml and 1000 ml multidose colourless plastic vials. Keep vial in outer carton. Not all pack sizes may be marketed

FOR ANIMAL TREATMENT ONLY
Vm 05653/4203
POM-VPS
U.K. authorised veterinary medicinal product
To be supplied on veterinary prescription

Distributed by Virbac Ltd, Suffolk, IP30 9UP, UK

Approved 11 April 2024