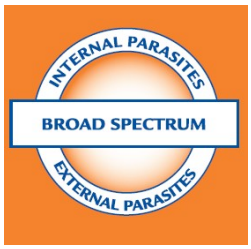
PARTICULARS TO APPEAR ON THE OUTER PACKAGE - Box of 200 ml, 500 ml and 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 1.0% w/v Solution for Injection for Cattle and Swine



2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin ……. 10 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

200 ml, 500 ml and 1000 ml.

5. TARGET SPECIES

Cattle and swine.

6. INDICATION(S)

CATTLE:
The product is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungworms, 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 helvetianus* (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.

Persistent activity in cattle

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with the product at the recommended dose rate controls re-infection with *Cooperia* spp., *Haemonchus placei* and *Trichostrongylus axei* for up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of the product, it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture. Treated animals should always be monitored according to good husbandry practices.

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*).

Recommended treatment programme Breeding animals:
At the time of initiating any parasite-control programme, it is important to treat all breeding animals in the herd. After the initial treatment, use the product regularly as follows:
- sows: treat 7-14 days prior to farrowing;
- gilts: treat 7-14 days prior to farrowing; treat 7-14 days prior to service;
- boars: frequency of and need for treatments are dependent upon exposure; treat at least twice per year.

Fatteners:
All pigs received for fattening should be treated before placement in clean quarters. Pigs exposed to soil may need re-treatment if re-infection occurs. All brought-in pigs should be isolated and treated with the product before being introduced to the herd.
The above programme is a guide for effective parasite control using the product. Alternatively, a wide measure of control may be achieved by "total-herd treatments" at six-monthly intervals. Note: for effective mange control, care must be taken to prevent re-infestation from exposure to untreated animals or contaminated facilities.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous route.

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 dairy cows including pregnant heifers within 60 days of calving.

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

9. SPECIAL WARNING(S), IF NECESSARY

CONTRAINDICATIONS
Do not use by the intravenous or intramuscular route.
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 and swine as severe adverse reactions including fatalities in dogs may occur.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Following withdrawal of the first dose, use the product within 3 months. Dispose of unused material. Avoid introduction of contamination. Protect from light. Keep the container in the outer carton.

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.

For posology and method of administration, undesirable effects, operator warnings, special precautions for use, use during pregnancy and lactation, overdosage, please read the package leaflet carefully.

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

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Distributed by:
Virbac Ltd
Windmill Avenue - Woolpit
Business Park - Woolpit - Bury St
Edmunds Suffolk IP30 9UP - UK.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4204

17. MANUFACTURER'S BATCH NUMBER

BN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – 200 ml, 500 ml and 1 L

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 1.0% w/v Solution for Injection for Cattle and Swine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ivermectin ……. 10 mg per ml

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

200 ml, 500 ml and 1000 ml.

5. TARGET SPECIES

Cattle and swine.

6. INDICATION(S)

Read package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous route.

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 dairy cows including pregnant heifers within 60 days of calving.

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

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP:

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Following withdrawal of the first dose, use the product within 3 months. Dispose of unused material. Avoid introduction of contamination. Protect from light.

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. **Read the package leaflet carefully before use.**

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

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

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

Distributed by:
VIRBAC Ltd- Suffolk IP30 9UP - UK.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/4204

17. MANUFACTURER'S BATCH NUMBER

BN:

PACKAGE LEAFLET FOR:

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

Virbamec 1.0% w/v Solution for Injection for Cattle and Swine

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

Ivermectin……10 mg per ml

4. INDICATION(S)

CATTLE: The product is indicated for the treatment and control of the following species of gastro-intestinal roundworms, lungworms, 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 helvetianus* (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.

Persistent activity in cattle

When cattle have to graze on pasture contaminated with infective larvae of cattle nematodes, treatment with the product at the recommended dose rate controls re-infection with *Cooperia* spp., *Haemonchus placei* and *Trichostrongylus axei* for up to 14 days after treatment, *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired up to 21 days and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

To obtain optimal benefit from the persistent activity of the product, it is recommended that calves which are set-stocked in their first grazing season should be treated 3, 8 and 13 weeks after the day of turn-out. This can protect the animals from parasitic gastro-enteritis and lungworm disease throughout the grazing season provided they are set-stocked, all the calves are included in the programme and that no untreated cattle are added to the pasture. Treated animals should always be monitored according to good husbandry practices.

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*).

Recommended treatment programme Breeding animals:
At the time of initiating any parasite-control programme, it is important to treat all breeding animals in the herd. After the initial treatment, use the product regularly as follows:
- sows: treat 7-14 days prior to farrowing;
- gilts: treat 7-14 days prior to farrowing; treat 7-14 days prior to service;
- boars: frequency of and need for treatments are dependent upon exposure; treat at least twice per year.

Fatteners:
All pigs received for fattening should be treated before placement in clean quarters.

Pigs exposed to soil may need re-treatment if re-infection occurs. All brought-in pigs should be isolated and treated with the product before being introduced to the herd.

The above programme is a guide for effective parasite control using the product. Alternatively, a wide measure of control may be achieved by "total-herd treatments" at six-monthly intervals. Note: for effective mange control, care must be taken to prevent re-infestation from exposure to untreated animals or contaminated facilities.

5. CONTRA-INDICATIONS

Do not use by the intravenous or intramuscular route.
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 and swine as severe adverse reactions including fatalities in dogs may occur.

6. ADVERSE REACTIONS

At therapeutic doses, ivermectin has no adverse effect on cattle or swine since it does not readily penetrate their central nervous systems. Transitory discomfort has been observed in some cattle and pigs following subcutaneous administration. A low incidence of soft tissue swelling at the injection site has been observed in both species. These reactions have disappeared without treatment.

OPERATOR WARNINGS

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

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.

USE DURING PREGNANCY AND LACTATION

Studies have shown a wide safety margin and, at the recommended dosage, no adverse effect on breeding performance were observed. Do not use in non-lactating dairy cows including pregnant heifers within 60 days of calving.

OVERDOSAGE

Cattle: Single doses of 4 mg ivermectin per kg (20 x the use level)

given subcutaneously resulted in ataxia and depression.

Swine: A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, labored breathing and lateral recumbency. For both cattle and swine, no antidote has been identified; however, symptomatic therapy may be beneficial.

8. POSOLOGY AND METHOD OF ADMINISTRATION

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

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: Injection at the recommended dosage level of 3 mg ivermectin per 10 kg bodyweight (equivalent to 1 ml per 33 kg bodyweight). Over 200 kg bodyweight, give 1.0 ml per 33 kg bodyweight. Inject subcutaneously in the neck in pigs.

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

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. 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.

Dosage schedule for swine

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

7. TARGET SPECIES

Cattle and Swine

9. ADVICE ON CORRECT ADMINISTRATION

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 dairy cows including pregnant heifers within 60 days of calving.

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

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C. When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package insert, 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.
Following withdrawal of the first dose, use the product within 3 months.
Dispose of unused material. Avoid introduction of contamination. Protect from light. Keep the container in the outer carton.

12. 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.

13. 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.

14. OTHER INFORMATION

200 ml, 500 ml and 1000 ml colourless multidose plastic vials.

POM-VPS

To be supplied only on veterinary

prescription. Vm 05653/4204

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Marketing authorisation holder and manufacturer:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Distributed by:
VIRBAC Ltd - Windmill Avenue - Woolpit Business Park - Woolpit - Bury St Edmunds
- Suffolk IP30 9UP - UK.

Approved 11 April 2024