SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ivermectin.....10 mg per ml

3. PHARMACEUTICAL FORM

Solution for injection.
Clear pale-yellow non-aqueous sterile solution.

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

Ivermectin is a highly-active, broad-spectrum, internal and external antiparasitic of the avermectin family.
Ivermectins are isolated after fermentation of the soil organism *Streptomyces avermitilis*.

Ivermectin acts by inhibiting nerve impulses.
Its mode of action includes γ-aminobutyric acid or GABA, neurotransmitter inhibitor at the level of presynaptic nerve terminations or at the level of neuromuscular junctions.
Ivermectin stimulates GABA liberation at presynaptic nerve terminations (in nematodes) or the neuromuscular junctions (in arthropodes, acarids, flies and fleas), which leads to the paralysis and death of the relevant parasites.

Acetylcholine, the main peripheric neurotransmitter, is not affected by ivermectin. Furthermore, ivermectin does not enter the central nervous system in the mammals, where GABA acts as neurotransmitter.

4.2 Pharmacokinetic properties

ATC Vet Code: QP54AA01

The biological half-life afforded by an injectable formulation is significantly longer than the intrinsic half-life of the drug (intravenous bolus). Slower absorption associated with the parenteral route (subcutaneous injection), compared to the oral administration, has been attributed to precipitation of the drug at the injection site.
The low solubility of ivermectin in water, its formulation in non-aqueous preparation and its deposition in the subcutaneous tissue favour a slow absorption from the site of injection, which may account for its prolonged

residence in the bloodstream.

In cattle
Following a subcutaneous administration of the recommended dosage (1 ml for 50 kg bodyweight), the elimination half-life is obtained after 15 hours with a plasma peak achieved after 50 hours. The concentrations progressively decrease with an elimination half-life of 128 hours. Studies have shown that the liver is the target tissue with the highest residue levels recovered. All other tissues showed lower residues: fat> kidney>muscle. The injection site had residues shortly after treatment but by day 28 the average residues were negligible. After administration of tritium-labelled ivermectin, faeces collected during the first 7 days after dosing contained almost all the dosed radioactivity. Only about 1 %-2 % of the dosed radioactivity was excreted in the urine. About 40 %-50 % of the excreted radioactivity was present as unaltered drug.

In swine
Following a subcutaneous administration of the recommended dosage (1 ml per 33 kg bodyweight), the ivermectin plasma peak is observed after 1.5 days with 13.71 ng/ml. The concentration then remains stable for 4 days (concentrations over Cmax /2) before decreasing with an elimination half-life of 1 day. Studies have shown that liver is the target tissue. Following an injection of 0.4 mg/kg, no liver residues (< 2ppb) were found at 28 days *post* dose. After administration of tritium-labelled ivermectin, faeces collected during the first 7 days after dosing contained only about 36 % of the dosed radioactivity. Less than 1 % of the dosed radioactivity was found in the urine. About 40 % of the excreted radioactivity was unaltered drug.

5. CLINICAL PARTICULARS

5.1 Target species

Cattle and swine.

5.2 Indications for use

CATTLE

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

Cooperia pectinata
Bunostomum phlebotomum

Oesophagostomum radiatum
Strongyloides papillosus (adult)
Nematodirus helvetianus (adult)
Nematodirus spathiger (adult)
Trichuris spp. (adult)

Lungworms (adult and fourth-stage larvae):

Dictyocaulus viviparus

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

Virbamec 1.0% w/v Solution for Injection for Cattle and Swine 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 Virbamec 1.0% w/v Solution for Injection for Cattle and Swine 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 Virbamec1.0% w/v Solution for Injection for Cattle and Swine, 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

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

Virbamec 1.0% w/v Solution for Injection for Cattle and Swine may also be used as an aid in the control of adult whipworm (*Trichuris suis*).

5.3 Contra-indications

Do not use by the intravenous or intramuscular route.
Do not use in cattle producing milk for human consumption.
Not for use in species other than cattle and swine as severe adverse reactions including fatalities in dogs may occur.

5.4 Undesirable effects

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.

5.5 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.

5.6 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.

5.7 Interaction with other medicaments and other forms of interaction

None known.

5.8 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.

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

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.

SWINE

Injection at the recommended dosage level of 3 mg ivermectin per 10 kg bodyweight (equivalent to 1 ml per 33 kg bodyweight).

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

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.

5.9 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.

5.10 Special warnings

None known.

5.11 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.

5.12 Special precautions to be taken by the person administering the product to animals

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.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf life

3 years.
In use shelf life: 3 months.

6.3 Special precautions for storage

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.

6.4 Nature and contents of container

Sizes: 200 ml, 500 ml and 1000 ml colourless multidose LDPE vials with plastic overcap covering rubber stopper and aluminium overseal.

Not all pack sizes may be marketed.

6.5 Special precautions for the disposal of unused product or waste material

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 used container.

7. MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

8. MARKETING AUTHORISATION NUMBER

Vm 05653/4204

9. DATE OF FIRST AUTHORISATION

06 October 2000

10. DATE OF REVISION OF TEXT

April 2024

FURTHER INFORMATION

Ivermectin belongs to the avermectin (3-AV) class of anthelmintic endectocides.
Chemical group of anthelmintic endectocides [3-AV].

Approved 11 April 2024