1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 5 mg/ml pour-on solution for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ivermectin ..... 5 mg

Excipients:

Qualitative composition of excipients and other constituents
Crodamol CAP or Cetearyl ethylhexanoate
Isopropyl myristate
Triethanolamine
Isopropyl alcohol

Pale yellow clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the treatment of gastro-intestinal nematodes, lungworms, warbles, chorioptic and sarcoptic mange mites, sucking and biting lice of beef and non-lactating dairy cattle.

Gastro-intestinal roundworms (adults and 4th stage larvae):

Ostertagia ostertagi	(L4, adults and inhibited stages)
Haemonchus placei	(L4, adults)
Trichostrongylus axei	(L4, adults)
Trichostrongylus colubriformis	(L4, adults)
Cooperia spp.	(adults)
Cooperia puntacta	(adults)
C*ooperia oncophora*	(adults)
Oesophagostomum radiatum	(L4, adults)
Strongyloides papillosus	(adults)
Trichuris spp.	(adults)

Lungworms (adults and 4th stage larvae):

Dictyocaulus viviparus

Warbles (parasitic stages):

Hypoderma bovis
Hypoderma lineatum

Mites:

Sarcoptes scabiei var bovis
Chorioptes bovis

Lice:

Sucking lice
Linognathus vituli
Haematopinus eurysternus

Biting lice
Damalinia bovis

The veterinary medicinal product, at the recommended use level of 500 mcg ivermectin per kg bodyweight, has a persistent activity on:

Dictyocaulus viviparus:	for up to 28 days
Ostertagia spp*:*	for up to 21 days
Oesophagostomum radiatum:	for up to 21 days
Cooperia spp.*:*	for up to 14 days
Trichostrongylus axei:	for up to 14 days

The veterinary medicinal product helps in the control of the mange mite *Chorioptes bovis* but complete elimination may not occur.

The veterinary medicinal product has also a persistent activity on the horn Fly (*Haematobia irritans)* for 28 days, partial efficacy may last for up to 35 days post application.

Occasionally variable activity may be observed against *Haemonchus placei* (L4), *Cooperia* spp, *Trichostrongylus axei* and *Trichostrongylus colubriformis.*

To obtain optimal benefit of veterinary medicinal product, the product is recommended to be used as part of treatment programs, based on the epidemiology of the parasites in question.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
This product is for application to skin surface only, do not inject or give orally.
Do not use in dairy cows, during lactation or the dry period, and in beef cows during the lactation period when milk is intended for human consumption.
Do not use in pregnant dairy heifers within 60 days prior to calving.

3.4 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:

- 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 *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 recommendations on how to limit further selection for resistance to anthelmintics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.

Cattle should not be treated when the hair or hide is wet. Rain falling on animals less than two hours after dosing may result in reduced efficacy. However, under such conditions efficacy of veterinary medicinal product against infections of *Ostertagia ostertagi* or *Dictyocaulus viviparus* in cattle may be maintained. The influence of extreme weather conditions on the long-term performance (persistent activity) of veterinary medicinal product is not known.

Frequent and repeated use may lead to the development of resistance.

The product is effective in all hypodermosis stages, however, it is very important to treat on time (at the end of warble fly season). The elimination of *Hypoderma* larvae may cause negative reactions on the host, when they are found in vital areas. Killing *Hypoderma lineatum*, if found in perioesophageal tissue, may cause salivation and tympanism. Killing *Hypoderma bovis*, if found in the vertebral canal, may cause unsteadiness or paralysis. Cattle should be treated before or after those stages of warble flies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Personal protective clothing consisting of nitrile rubber gloves, rubber boots and a waterproof coat should be worn when handling the veterinary medicinal product.
Protective clothing should be washed after use.

In case of accidental spillage onto skin, wash the affected area immediately with soap and water. In case of accidental eye exposure, flush the eyes immediately with water and seek medical advice and show the package leaflet or the label to the physician.

Do not smoke or eat while handling the product.

Wash hands after use.

Use only in well ventilated areas or outdoors.

Highly flammable.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:
Avermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use in dairy cows during lactation or the dry period, and in beef cows during the lactation period when milk is intended for human consumption.
Do not use in pregnant dairy heifers within 60 days prior to calving.
See also section 3.12.

3.8 Interaction with other medicinal products and other forms of interaction

Do not combine treatment with vaccination against lungworm infection. If vaccination is intended, an interval of at least 28 days before or after the date of vaccination should be taken into account.

3.9 Administration routes and dosage

Posology:
1 ml per 10 kg bodyweight (based on a recommended dosage level of 500 mcg ivermectin per kg bodyweight).

Administration:
Pour-on use.

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

The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.

500 ml and 1L bottles

Both are equipped with a Squeeze-Measure-Pour System.

Attach the metering cup firmly to the bottle.

Set the dose by turning the top section of the cup to align the correct bodyweight. When bodyweight is between markings, use the higher setting.

Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.

When the pressure is released, the dose automatically adjusts to the correct level. Tilt the bottle and dispense the solution.

Important- Keep upright when filling and during storage.

Close container when not in use and store in an upright position.

2.5 litre backpack and 5 litre backpack

These presentations are equipped with straps and a vented cap.

They should be used in conjunction with an appropriate dosing gun.

Connect the Pour-On applicator to the pack as follows:

Attach the open end of the draw-off tubing to the Pour-On applicator.

Attach draw-off tubing to the cap with the stem. Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.

Gently prime the Pour-On applicator, checking for leaks.

Follow manufacturer's directions for correct use and care of the equipment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Studies have demonstrated a wide safety margin. No sign of toxicity appeared in trials up to 5 mg/kg (10 times the recommended dose rate). No antidote has been identified.
In case of overdose, symptomatic treatment should be given. The symptoms of overdose can be trembling, convulsions and coma.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.

Not authorised for use in animals producing milk for human consumption.
Do not use in pregnant cows, which are intended to produce milk for human consumption, within 60 days of expected parturition.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP 54AA01

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

After administration of the recommended dosage to cattle varying inter-individual ivermectin plasma levels were observed with mean values of C_{max} and t_{max} of 17 ng/ml and 170 h, respectively.
After topical administration of 0.5 mg ivermectin per kg bodyweight, liver and fat (the target tissues), generally had the highest residues. Excretion occurs mainly through faeces and, in lesser proportion, via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Highly flammable. Do not smoke.
Keep away from heat, sparks, open flames or other sources of ignition.
Store the veterinary medicinal product in the original container and keep tightly closed.
Keep the container in the outer carton in order to protect from light.
The container should be stored in an upright position.
If stored at low temperatures below 0°C, the veterinary medicinal product may appear cloudy.
Allowing to warm at room temperature will restore the normal appearance without affecting efficacy.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is available in either 500 ml and 1 litre packs with a squeeze-measure-pour system or a 2.5 litre or 5.0 litre backpack with a draw-off cap.

Size: 500 ml and 1L
Container: Opaque high density polyethylene bottle.
Closure: Low density polyethylene seal fitted with a child resistant screw cap.
Dosing device: separate measuring chamber, made of polypropylene, capable of delivering doses of 10 to 25 ml at 5 ml intervals.

Size: 2.5 L and 5 L
Container: Opaque high density polyethylene pack.
Closure: Low density polyethylene seal fitted with a child resistant screw cap.
Dosing device: made of polypropylene, to be used in conjunction with a dosing gun.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin is extremely dangerous for fish and other aquatic organisms.
Treated animals should not have direct access to surface waters or ditches. Do not contaminate surface waters or ditches with the product or used container.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10988/106/001

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/04/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

31/05/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).