SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivermectin pour-on solution for cattle 5 mg/ml Virbac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance
Ivermectin 5.0 mg/ml
Excipient(s):
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on solution.
Clear, colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

Ivermectin pour-on solution for cattle 5 mg/ml Virbac 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
Ostertagia ostertagi (L4, adults and inhibited stages)
Haemonchus placei (L4, adults)
Trichostrongylus axei (L4, adults)
Trichostrongylus colubriformis (L4, adults)
Cooperia spp. (adults)
Cooperia punctata (adults)
Cooperia 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 product, at the recommended use level of 500 µg/kg of ivermectin, 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 product helps in the control of the mange mite Chorioptes bovis but complete elimination may not occur.
The 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 Premadex Pour On Solution for Cattle 5 mg/ml, the product is recommended to be used as part of treatment programs, based on the epidemiology of the parasites in question.

4.3 Contra-indications

Do not use in animals known to be hypersensitive to the active substance or to any of the ingredients.
Do not inject or give orally. This product is for application to skin surface only.
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.

4.4 Special warnings for each target species

Assess bodyweight as accurately as possible before calculating the dosage.
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 the 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 the product is not known.
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 Cooperia oncophora in cattle within the EU. Therefore the use of this product should be based on local (regional and farm) epidemiological information about susceptibility of the gastrointestinal nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

4.5 Special precautions for use

i. Special precautions for use in animals

Do not apply to areas of skin which have mange scabs or other lesions or to areas contaminated with mud or manure.
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.
The product is effective in all hypodermosis stages. However, it is 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.

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

HIGHLY FLAMMABLE - keep away from heat, sparks, open flame or other sources of ignition.
The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear nitrile rubber gloves, rubber boots and a waterproof coat when applying the product. Protective clothing should be washed after use.
If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.
Do not smoke, drink or eat while handling the product.
Wash hands after use.
Use only in well-ventilated areas or outdoors.

iii. Other precautions

Treated cattle should not have direct access to ponds, streams or ditches for 14 days after treatment.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

See section 4.3 Contraindications

4.8 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.

4.9 Amounts to be administered and administration route

Posology
1 ml per 10 kg of bodyweight (based on a recommended dosage level of 500 µg/kg of ivermectin.
Administration
Pour-on use. The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead.
To ensure correct administration of a correct dose:
i. bodyweight should be determined as accurately as possible;
ii. accuracy of the dosing device should be checked.
500 ml and 1 litre 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 with 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 and 5 litre backpacks
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 directions for correct use and care of the equipment.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period

Cattle
Meat and offal: 28 days.
Not permitted for use in lactating cows 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: endectocide.
ATCvet code: QP54AA01.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

5.3 Environmental properties

In laboratory studies ivermectin has been shown to be highly toxic to aquatic invertebrates.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crodamol CAP or Cetearyl ethylhexanoate and isopropylmyristate
Triethanolamine
Isopropyl alcohol.

6.2 Incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Highly flammable. Keep away from heat sparks, open flames or other sources of ignition.
Store the 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 this product may appear cloudy. Allowing to warm to room temperature will restore the normal appearance without affecting efficacy.

6.5 Nature and composition of immediate packaging

This 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.
500 ml and 1 litre opaque high-density polyethylene bottle fitted with a child resistant cap (screw fit) containing an internal low density polyethylene seal. Supplied with a polypropylene dosing device capable of delivering doses of 10 to 25 ml, at 5 ml intervals.
2.5 and 5 litre opaque high density polyethylene pack fitted with a child resistant cap (screw fit) containing an internal low density polyethylene seal. To be used with a polypropylene dosing device in conjunction with a dosing gun.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with the product or used container.

7. MARKETING-AUTHORISATION HOLDER

Virbac S.A.
1ère avenue , 2065m - LID
06516 Carros
Cedex
France

8. MARKETING-AUTHORISATION NUMBER

Vm 05653/4149

9. DATE OF FIRST AUTHORISATION

Date: 23 October 2008

10. DATE OF REVISION OF THE TEXT

Date: April 2015

APPROVED T. NASH **30/04/15**