

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

500 ml, 1 litre bottle
2.5 litre, 5 litre pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 5 mg/ml

3. PACKAGE SIZE

500 ml
1 L
2.5 L
5 L

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour on use.
Apply along the mid-line of the back in a narrow strip between the withers and tailhead.

7. 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBER

Vm 05653/3030

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

500 ml, 1 litre bottle
2.5 litre, 5 litre pack

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Virbamec 5 mg/ml pour-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Ivermectin 0.5 % w/v (5 mg/ml)

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Pour on use.
Apply along the mid-line of the back in a narrow strip between the withers and tailhead.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Meat and offal: 28 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use by...

7. SPECIAL STORAGE PRECAUTIONS

Highly flammable. Do not smoke.
Keep away from heat, sparks, open flames or other sources of ignition.
Store the product in the original container in order to protect from light and keep tightly closed 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.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Virbamec 5 mg/ml pour-on solution for cattle

2. Composition

Ivermectin0.5 % w/v (5 mg/ml)

Pale yellow clear solution.

3. Target species

Cattle

4. Indications for use

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):

<i>Ostertagia ostertagi</i>	(L4, adults and inhibited stages)
<i>Haemonchus placei</i>	(L4, adults)
<i>Trichostrongylus axei</i>	(L4, adults)
<i>Trichostrongylus colubriformis</i>	(L4, adults)
<i>Cooperia</i> spp.	(adults)
<i>Cooperia punctata</i>	(adults)
<i>Cooperia oncophora</i>	(adults)
<i>Oesophagostomum radiatum</i>	(L4, adults)
<i>Strongyloides papillosus</i>	(adults)
<i>Trichuris</i> 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:

<i>Dictyocaulus viviparus:</i>	for up to 28 days
<i>Ostertagia</i> spp:	for up to 21 days
<i>Oesophagostomum radiatum:</i>	for up to 21 days
<i>Cooperia</i> spp.:	for up to 14 days
<i>Trichostrongylus axei:</i>	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

5. 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.

6. Special warnings

Special warning:

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.

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.

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.

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.

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.

7. Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder

using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Posology:

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

Administration:

Topical administration.

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.

9. Advice on correct administration

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.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

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.

Storage temperature: none.

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.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

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

This 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 05653/3030

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.

Not all pack sizes may be marketed.

15. 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.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

VIRBAC
1^{ère} avenue 2065m LID
06516 Carros
France

Manufacturer responsible for batch release:

VIRBAC
1^{ère} avenue 2065m LID
06516 Carros
France

Local representative(s) and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.



Approved 13 November 2024
Gavin Hall