PARTICULARS TO APPEAR ON THE OUTER PACKAGE (1000 ml, 500 ml, 200 ml and 50 ml cartons)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Super Injection for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substances:
Ivermectin 10 mg
Clorsulon 100 mg

3. PACKAGE SIZE

50 ml
200 ml
500 ml
1000 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous
The veterinary medicinal product should be given only by subcutaneous injection behind the shoulder.
Divide doses greater than 10 ml between two injection sites. A sterile 17-gauge 1/2-inch needle is recommended. When the temperature of the product is below 5 °C, difficulty in administration may be encountered due to increased viscosity. Warming the veterinary medicinal product and injection equipment to about 15 °C will greatly increase the ease with which the veterinary medicinal product can be injected.
Different injection sites should be used for other parenteral products.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 66 days.
Do not use in cattle producing milk for human consumption, or in non-lactating dairy cows including pregnant heifers within 60 days of calving.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

Protect from light.

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 SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 61700/5020
Vm 61700/3031

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (1000 ml, 500 ml, 200 ml and 50 ml labels)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ivomec Super Injection for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substances:

Ivermectin	10 mg
Clorsulon	100 mg

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Subcutaneous.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 66 days.
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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use withing 6 months.

7. SPECIAL STORAGE PRECAUTIONS

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Ivomec Super Injection for Cattle

2. Composition

Each ml contains:

Active substances:

Ivermectin 10 mg
Clorsulon 100 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol formal
Propylene Glycol

A clear, slightly yellow-coloured solution.

3 Target species

Cattle.

4. Indications for use

The veterinary medicinal product is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, liver fluke, eyeworms, warbles, mites and lice.

Gastrointestinal roundworms (Adults and fourth-stage larvae)
Ostertagia ostertagi (including inhibited larval stages), *O. lyrata, Haemonchus placei, Trichostrongylus axei, Trichostrongylus colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Bunostomum phlebotomum, Oesophagostomum radiatum, Strongyloides papillosus* (adult), *Nematodirus helvetianus* (adult), *N. spathiger* (adult), and *Trichuris* spp. (adult)

Lungworms (Adult and fourth-stage larvae)
Dictyocaulus viviparus

Liver fluke (Adult)
Fasciola hepatica

Eyeworms (Adult)
Thelazia spp.

Warbles (parasitic stages)
Hypoderma bovis, H. lineatum

Mange mites
Psoroptes bovis, Sarcoptes scabiei var. *bovis*

Sucking Lice
Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

The veterinary medicinal product may also be used as an aid in the control of biting lice (*Damalinia bovis)* and the mange mite (*Chorioptes bovis)*, but complete elimination may not occur.

Prolonged activity
The veterinary medicinal product remains highly effective against newly ingested larvae of important parasites grazed from the pasture for an extended period after treatment.Treatment with the veterinary medicinal product at the recommended dose rate controls re-infection with *Haemonchus placei, Cooperia* spp. and *Trichostrongylus axei* acquired up to 14 days after treatment; *Ostertagia* spp. and *Oesophagostomum radiatum* acquired up to 21 days after treatment and *Dictyocaulus viviparus* acquired up to 28 days after treatment.

5. Contraindications

Do not use intramuscularly or intravenously.
This veterinary medicinal product is a low-volume product registered for use in cattle. Do not use in other species as severe adverse reactions, including fatalities in dogs, may occur.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

PRECAUTIONS

Special warnings:
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 bodyweight, misadministration of the product, or lack of calibration of the dosing device.

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 macrocyclic lactones (which includes ivermectin) has been reported in *Cooperia* spp. in cattle within 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:
The veterinary medicinal product does not contain an antimicrobial preservative.
Swab the septum before removing each dose.
Use a dry sterile needle and syringe.

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

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

Pregnancy and lactation:
The veterinary medicinal product is safe for use at any stage of pregnancy or lactation. However, the veterinary medical product is not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

Fertility:
The veterinary medical product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
The administration of 25 ml of the veterinary medical product per 50 kg bodyweight (25x the recommended dose level) resulted in injection site lesion (including tissue necrosis, oedema, fibrosis and inflammation). No other drug-related adverse reactions could be determined.

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1], discomfort[1]

[1] following subcutaneous injection, resolves without treatment

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

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

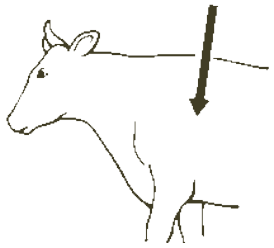
8. Dosage for each species, routes and method of administration

Dosage:
The veterinary medicinal product should be administered onlyby subcutaneous injection at the recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kg of bodyweight. Each ml contains 10 mg of ivermectin and 100 mg of clorsulon, sufficient to treat 50 kg of bodyweight. Use the following dosage schedule:

Bodyweight kg	Dose Volume ml	Bodyweight kg	Dose Volume ml
Up to 50	1.0	301-350	7.0
51-100	2.0	351-400	8.0
101-150	3.0	401-450	9.0
151-200	4.0	451-500	10.0
201-250	5.0	501-550	11.0
251-300	6.0	551-600	12.0

Divide doses greater than 10 ml between two injection sites.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Administration:
The veterinary medicinal product is to be given subcutaneously only.
Inject under the loose skin behind the shoulder (see illustration).

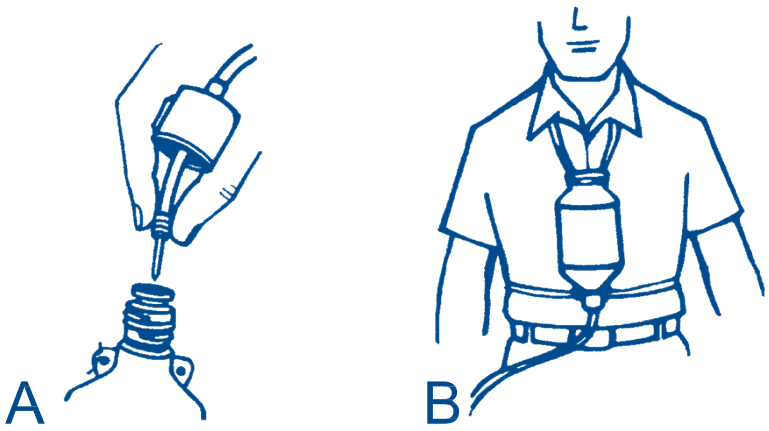


Use of a 17-gauge, 1/2 inch (15-20 mm) needle is recommended. Injection of animals with wet or dirty hides is not recommended.
If using a hypodermic syringe, use a separate sterile needle to withdraw the veterinary medicinal productfrom the pack.
When the temperature of the veterinary medicinal product is below 5 °C, difficulty in administration may be encountered due to increased viscosity. Warming the veterinary medicinal product and injection equipment to about 15 °C will greatly increase the ease with which the veterinary medicinal product can be injected.
Different injection sites should be used for other parenteral products.

9. Advice on correct administration

When using the 200 ml, 500 ml and 1000 ml pack sizes, use only automatic syringe equipment.

Instructions for use with automatic injection equipment:
- Disinfect all needles and syringes before using by boiling in clean water for 15-20 minutes.
- Boiled needles should be stored in an antiseptic solution before use and changed frequently when injecting cattle.
- The use of a sterile draw-off assembly is recommended with this product. Handle carefully to avoid contamination.
- Connect the plastic tube firmly to the dosing syringe. Use a stepped adaptor if needed.
- Remove cap from bottle and disinfect rubber stopper with alcohol or other suitable chemical disinfectant. Hold bottle upright and fully insert draw-off needle into centre of rubber stopper (see illustration A). Secure firmly with screw-on cap attached to tube.
- Hang bottle comfortably in inverted position from neck (see illustration B), shoulder or belt.
- Gently prime injector. Equipment is now ready for use.
- After use, remove draw-off assembly and flush out entire apparatus with clean water before storing.
- Store partly-used bottle in carton to protect from light. Do not re-use empty bottles.
- If the connecting tube is used a second time, it should also be boiled for 15-20 minutes before use along with the injecting syringe and needles.



10. Withdrawal periods

Meat and offal: 66 days.
Milk: 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.

11. Special storage precautions

Keep out of the sight and reach of children,
Protect from light.
Following withdrawal of the first dose, use product within 6 months.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

12 Special precautions for disposal

Medicines should not be disposed of via wastewater.

Container disposal: **EXTREMELY DANGEROUS TO FISH AND AQUATIC LIFE.**
Do not contaminate surface waters or ditches with the veterinary medicinal product or used containers.
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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 61700/5020
Vm 61700/3031

Multiple-dose rubber-capped polyethylene bottles of 50 ml, 200 ml, 500 ml and 1000 ml. Bottles are stoppered and then either sealed by heat or crimp-sealed with an aluminium 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:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
+353 1 291 3985

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 Toulouse
France

17. Other information

POM-VPS

Introduction
The veterinary medicinal product is an injectable parasiticide. One low-volume dose effectively kills internal and external parasites that impair the health and productivity of cattle. The veterinary medicinal product contains ivermectin and the flukicide, clorsulon. Its convenience, broad-spectrum efficacy, and wide safety margin make it an ideal veterinary medicinal product for parasite control of cattle.

Product description
The veterinary medicinal product is a sterile, non-aqueous solution containing 10 mg/ml ivermectin and 100 mg/ml clorsulon for parenteral administration.
At the rate of 1 ml per 50 kg bodyweight by subcutaneous injection, this formulation delivers the recommended dosage level of 200 mcg ivermectin and 2 mg clorsulon per kg bodyweight.

Mode of action
Ivermectin paralyses and ultimately kills parasitic nematodes, arachnids and insects, including warbles, by its effect on the nervous systems of these parasites. At therapeutic doses, ivermectin has no adverse effect on cattle since it does not readily penetrate their central nervous systems. Ivermectin belongs to the avermectin class of anthelmintic endectocides. The mode of action exhibited by the avermectins is unique to this class of antiparasitic agents. Clorsulon works by interrupting the metabolic activity of liver fluke and inhibiting enzymes that are essential for their energy production.

Product advantages

Low-volume Injection:
The veterinary medicinal product is highly effective against internal and external parasites at a dose volume of 1 ml per 50 kg bodyweight. It can be administered quickly and easily.

Broad Spectrum:
The veterinary medicinal product provides broad-spectrum efficacy against roundworms (including inhibited *Ostertagia*), lungworms, adult liver fluke, eyeworms, warbles, mange mites and lice.

Prolonged Activity:
The veterinary medicinal product remains highly effective against newly ingested larvae of important parasites grazed from the pasture for an extended period after treatment. Re-infection with lungworm is controlled for up to 28 days after treatment and important roundworms (*Ostertagia* spp. and *Cooperia* spp.) for up to 21 days and 14 days respectively.
The veterinary medicinal product contains ivermectin and clorsulon. The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing program should be established by a qualified professional person.

Safety
Studies have demonstrated a wide safety margin and the recommended use level had no adverse effect on breeding performance.

Gavin Hall
Approved: 02 December 2025