IVOMEC® Plus
(ivermectin/clorsulon) Injection
for Cattle

Parasiticide Injection

NADA No.: 140-833

Active Ingredient(s): IVOMEC® Plus is a ready-to-use sterile solution containing 1% w/v ivermectin, 10% clorsulon, 40% glycerol formal, and propylene glycol, q.s. ad 100%.

Indications: For the treatment and control of internal parasites, including adult liver flukes, and external parasites.

IVOMEC® Plus Injection is indicated for the effective treatment and control of the following parasites of cattle:

Gastrointestinal Roundworms (adults and fourth-stage larvae): *Ostertagia ostertagi* (including inhibited *O ostertagi*), *O lyrata*, *Haemonchus placei*, *Trichostongylus axei*, *T colubriformis*, *Cooperia oncophora*, *C punctata*, *C pectinata*, *Bunostomum phlebotomum*, *Nematodirus helvetianus* (adults only), *N spathiger* (adults only), *Oesophagostomum radiatum*.

Lungworms (adults and fourth-stage larvae): *Dictyocaulus viviparus*.

Liver Flukes: *Fasciola hepatica* (adults only).

Cattle Grubs (parasitic stages): *Hypoderma bovis*, *H lineatum*.

Sucking Lice: *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*.

Mange Mites (cattle scab*): *Psoroptes ovis* (syn. *P communis var. bovis*), *Sarcoptes scabiei var. bovis*.

Persistent activity: IVOMEC® has been proved to effectively control infections and to protect cattle from re-infection with *Dictyocaulus viviparus* for 28 days and *Ostertagia ostertagi* for 21 days after treatment;
Oesophagostomum radiatum, Haemonchus placei, Trichostrongylus axei, Cooperia punctata, and Cooperia oncophora for 14 days after treatment.

*Ivermectin has been approved as a scabicide by USDA/APHIS. Federal regulations require that cattle infested with or exposed to scabies (i.e., infestations with Psoroptes ovis) be treated. Ivermectin when used according to label instructions meets this requirement. Treated cattle may be shipped interstate, but they must not be mixed with other cattle for 14 days following treatment. The federal regulations make no restriction on the movement of cattle not affected with or exposed to scabies. However, individual states have additional regulations to govern the interstate shipment of cattle and the regulatory veterinarian in the state of destination should be consulted for applicable regulations on the use of ivermectin in the control of scabies.

Pharmacology: Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of the class bind 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 parasite. 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 wide margin of safety 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.

Clorsulon is rapidly absorbed into the circulating blood. Erythrocytes with bound drug as well as plasma are ingested by Fasciola hepatica. Adult Fasciola hepatica are killed by clorsulon because of inhibition of enzymes in the glycolytic pathway, which is their primary source of energy.

Dosage and Administration: It is formulated to deliver the recommended dose level of 200 mcg ivermectin/kg and 2 mg clorsulon/kg given subcutaneously behind the shoulder at the rate of 1 mL per 110 lb (50 kg) body weight.

IVOMEC® Plus should be given only by subcutaneous injection at a dose volume of 1 mL per 110 lb (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon. For example:
The dosage level of clorsulon supplied by IVOMEC® Plus is effective only against adult liver flukes (*Fasciola hepatica*).

IVOMEC® Plus Injection is to be given subcutaneously only. Animals should be appropriately restrained to achieve the proper route of administration. Use of a 16-gauge, ½" to ¾" sterile needle is recommended. Inject the solution subcutaneously (under the skin) behind the shoulder (see illustration).

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Any single-dose syringe or standard automatic syringe equipment may be
used with the 50 mL pack size. When using the 200 mL or 500 mL pack size, use only automatic syringe equipment.

Use sterile equipment and sanitize the injection site by applying a suitable disinfectant. Clean, properly disinfected needles should be used to reduce the potential for injection site infections.

No special handling or protective clothing is necessary.

The viscosity of the product increases in cool temperatures. Administering IVOMEC® Plus (ivermectin and clorsulon) at temperatures of 5°C (41°F) or below may be difficult. Users can make dosing easier by warming both the product and injection equipment to about 15°C (59°F).

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

**Contraindication(s):** IVOMEC® Plus Injection has been developed specifically for use in cattle only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

**Precaution(s):** Protect from light.

Environmental Safety: Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free ivermectin may adversely affect fish and certain water-borne organisms on which they feed. Do not permit water runoff from feedlots to enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

**Caution(s):** For subcutaneous injection in cattle only.

This product is not for intravenous or intramuscular use.

IVOMEC® Plus effectively controls all stages of cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble fly) season.

Destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *Hypoderma lineatum* when it is in the tissue surrounding the esophagus (gullet) may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with IVOMEC® Plus, but can occur with any successful treatment of grubs. Cattle should be treated either before or after stages or grub development. Consult your veterinarian.
concerning the proper time for treatment.

Cattle treated with IVOMEC® Plus after the end of the heel fly season may be retreated with ivermectin during the winter for internal parasites, mange mites or sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

Transitory discomfort has been observed in some cattle following subcutaneous administration. Soft-tissue swelling at the injection site has also been observed. These reactions have disappeared without treatment. Divide doses greater than 10 mL between two injection sites to reduce occasional discomfort or site reaction. Different injection sites should be used for other parenteral products.

**Warning(s):** Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

Keep this and all drugs out of the reach of children.

**Safety:** In breeding animals (bulls and cows), ivermectin and clorsulon used at the recommended level had no effect on breeding performance.

**Presentation:** IVOMEC® Plus Injection is available in three ready-to-use pack sizes:

- The 50 mL pack is a multiple-dose, rubber-capped bottle. Each bottle contains sufficient solution to treat 10 head of 550 lb (250 kg) cattle.

- The 200 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 40 head of 550 lb (250 kg) cattle.

- The 500 mL pack is a soft, collapsible pack designed for use with automatic syringe equipment. Each pack contains sufficient solution to treat 100 head of 550 lb (250 kg) cattle.

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Disclaimer: Every effort has been made to ensure the accuracy of the information published. However, it remains the responsibility of the readers to familiarize themselves with the product information contained on the product label or package insert. Compendium Code No.: 08491034

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