

Product Name: ICON-F BROADSPECTRUM ANTIPARASITIC INJECTION FOR CATTLE

APVMA Approval No: 90692/144682

Label Name: ICON-F BROADSPECTRUM ANTIPARASITIC INJECTION FOR CATTLE	
---	--

Signal Headings: **CAUTION** 

> KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS

Constituent 100 mg/mL CLORSULON 10 mg/mL IVERMECTIN Statements:

Claims:

For the treatment and control of ivermectin and clorsulon sensitive strains of internal and external parasites of cattle, including adult liver flukes.

ICON-F INJECTION contains ivermectin, a member of the macrocyclic lactone family of chemicals, which is effective against internal and external parasites sensitive to this family. It also contains clorsulon, a sulphonamide, which controls adult liver fluke.

ICON-F INJECTION is effective against sensitive strains of the following internal and external parasites.

Gastrointestinal roundworms

Adult and immature stages:

Ostertagia ostertagi - Small Brown Stomach Worm (including third and fourth stage larvae and inhibited fourth stage larvae)

O. Ivrata - Brown Stomach Worm

Haemonchus placei - Barber's Pole Worm (including third and fourth stage larvae)

Trichostrongylus axei - Stomach Hair Worm

Trichostrongylus colubriformis - Intestinal Hair Worm

Cooperia spp. - Small Intestinal Worm (including third and fourth stage larvae)

Oesophagostomum radiatum – Nodule Worm (including third and fourth stage larvae)

Bunostomum phlebotomum – Hookworm (including third and fourth stage larvae)

Adult stages of:

Nematodirus spathiger, Nematodirus helvetianus - Thin Necked Intestinal Worm

Strongyloides papillosus - Intestinal Threadworm

Toxocara vitulorum - Large Roundworm

Trichuris spp. - Whipworm

Adult Liver Fluke: Fasciola hepatica

Lungworm: Dictyocaulus viviparus (adult and immature) including inhibited stages.

Eyeworm: Thelazia spp. (adult stages).

Screw Worm Fly: Chrysomya bezziana (parasitic larval stages) (not reported in Australia but present in Papua-New Guinea).

Sucking Lice: Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus

Does not provide full control of the cattle biting louse, Bovicola (Damilinia) bovis.

Mites: Sarcoptes scabei var. bovis

Cattle tick: Rhipicephalus (Boophilus) microplus including organophosphate, synthetic pyrethroid and amidine resistant strains. Maximum efficacy is reached 4-5 days after treatment. Engorged female ticks that drop from cattle in the initial days after treatment may lay viable eggs. This should be taken into account when planning a strategic tick control program. ICON-F INJECTION should be alternated with conventional dips or pour-ons when the program requires repeat treatments.

## PERSISTENT ACTIVITY

At the recommended dose rate, ICON-F INJECTION effectively controls infections with Ostertagia spp. and Cooperia spp. acquired up to at least 7 days after treatment, and Dictyolcaulus viviparous and Chrysomyia bezziana acquired up to at least 14 days after treatment. When used as directed for the control of internal parasites of cattle, ICON-F INJECTION concurrently aids in control of:

Mites: Chorioptes bovis

Resistance may develop to any chemical.

Net Contents:	50 mL 200 mL 500 mL 6 x 500 mL 1 L
Directions for Use:	
Restraints:	
Contraindications:	
Precautions:	
Side Effects:	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.
Dosage and Administration:	Use the contents within 24 hours of first broaching of the vial. Discard the unused portion.

ICON-F INJECTION is to be given by subcutaneous injection only.

kg and 2 mg clorsulon per kg liveweight).

The recommended dose is 1 mL per 50 kg liveweight (equivalent to 0.2 mg ivermectin per

Inject under loose skin high on the neck, behind the ear in an area away from the more valuable carcass muscle. Loose skin on the neck in front of the shoulder is also a suitable site. This product is not to be used intravenously or intramuscularly.

Liveweight (kg) Dose volume (mL) Up to 100 2 101 - 150 3

4 151 - 200 5 201 - 250 251 - 300 6 7 301 - 350 351 - 400 8 401 - 450 9 451 - 500 10 501 - 550 11 12 551 - 600

13

601 - 650

Cattle heavier than 650 kg should be dosed at 1 mL per 50 kg. A representative sample of animals should be weighed before treatment either with scales or a weighband. Dose rate to be based on the heaviest cattle in each group (bulls, cows, steers, calves, etc.) Do not underdose. Where there is a large variation in size within the group, draft into two or more lines based on bodyweight, to avoid excessive overdosing.

### General Directions:

ICON-F INJECTION is an injectable parasiticide for cattle. One low-volume dose effectively kills internal parasites (including adult liver fluke) and external parasites that impair the health and productivity of cattle. The convenience and broad-spectrum efficacy of ICON-F INJECTION make it an ideal product for effective parasite control.

PRODUCT DESCRIPTION ICON-F INJECTION is a ready-to-use, sterile solution of ivermectin and clorsulon. Ivermectin is derived from the avermectins, a family of potent broad-spectrum antiparasitic agents which are isolated from fermentation of the naturally occurring soil-organism Streptomyces avermitilis. Clorsulon is for the treatment of adult liver fluke.

ICON-F INJECTION is formulated to deliver the recommended dosage level of 0.2 mg ivermectin and 2 mg clorsulon per kg liveweight when given subcutaneously at the rate of 1 mL/50 kg liveweight.

MODES OF ACTION 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 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 bloodbrain barrier.

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

NOTES TO USERS 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.

When the temperature of the product is below 5 °C, difficulty in administration may be encountered due to increased viscosity. Warming the product and injection equipment to about 15 °C will greatly increase the ease with which the product can be injected.

#### CAUTION: AVOID CARCASE DAMAGE

- 1. Sterilise all injection apparatus by boiling before use. Plastic disposable syringes should not be boiled. Avoid use of strong disinfectants on apparatus.
- 2. Maintain cleanliness at all times.
- 3. Keep needles sharp and clean. Replace frequently.
- 4. Use shortest needle possible, certainly not exceeding 15 mm.
- 5. As far as possible, avoid injection of animals during wet weather or under dusty conditions.
- 6. The product should be injected only under the skin.
- 7. If possible, inject high on the neck, behind the ear. Injection should be made only under loose skin in an area away from the more valuable carcass muscle. Loose skin on the neck in front of the shoulder is also a suitable area.

USING ICON-F INJECTION FOR BEST RESULTS Treatments with ICON-F INJECTION generally should be timed to use its antiparasitic properties to prevent development or build-up of parasitic infections. Resistance may develop to any chemical. For detailed advice on a program of parasite control you should consult your veterinarian.

### STERILE DRAW OFF ASSEMBLY

Instructions for use with automatic injection equipment:

- Use sterile equipment
- · Connect open end of tube firmly to injector
- Remove cap from bottle and disinfect rubber stopper. Hold bottle upright. Remove protective cap and fully insert draw-off needle into centre of rubber stopper. Secure screw on cap of draw-off assembly firmly to the bottle.
- Gently prime the injector to expel any air. Equipment is now ready for use.
- After use, remove draw-off assembly from pack and flush entire apparatus with water before storing.
- · Replace cap.
- If the connecting tube is used again, it should also be boiled for 15-20 minutes before use along with the injecting syringe and needles.

# PRODUCT ADVANTAGES

Low-volume injection The low-volume dosage level of ICON-F INJECTION makes it convenient for use with most syringes or automatic injectors. ICON-F INJECTION reduces the need for separate drenching, dipping and spraying operations common in the past, to control liver fluke and certain external parasites.

Broad Spectrum ICON-F INJECTION provides broad-spectrum efficacy against roundworms, adult liver flukes, lungworm, eyeworm, sucking lice, mites and cattle tick.

Safety Studies done with similar products have demonstrated a wide margin of safety. Pregnant and breeding cattle may be treated provided normal care is taken in handling.

NOT TO BE USED FOR ANY PURPOSE, OR IN ANY MANNER, CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

Withholding Periods:

MEAT: DO NOT USE less than 28 days before slaughter for human consumption. MILK: Zero (0) days.

Trade Advice:

EXPORT SLAUGHTER INTERVAL (ESI): DO NOT USE less than 42 days before slaughter for export. Before using this product, confirm the current ESI from Alleva Animal Health on 1-800 ALLEVA (1-800 255 382) or the APVMA website (apvma.gov.au/residues).

Safety Directions: Poisonous if swallowed. Avoid contact with eyes, skin and clothing.

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
First Aid Warnings:	
Additional User Safety:	Additional information is listed in the safety data sheet (SDS).
Environmental Statements:	ENVIRONMENTAL PROTECTION Ivermectin is extremely toxic to aquatic species. Do not contaminate dams, rivers, streams or other waterways with the chemical or used container.
Disposal:	Dispose of container by wrapping with paper and putting in garbage.
Storage:	Store below 30 °C (room temperature). Store bottle in carton to protect from light.