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MERCK ANIMAL HEALTH
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Imizol®

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Intervet/Merck Animal Health

(IMIDOCARB DIPROPIONATE)

NADA #141-071, Approved by FDA.

NDC 0061-5158-01

Each mL contains 120 mg of imidocarb dipropionate.

Sterile solution for intramuscular or subcutaneous injection.

CAUTION: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

IMIZOL (imidocarb dipropionate) is a sterile solution containing 120 mg/mL of imidocarb dipropionate suitable for intramuscular or subcutaneous administration. Imidocarb is chemically described as *N,N'*-bis[3-(4,5-dihydro-1*H*-imidazol-2-yl)-phenyl]urea dipropionate and has a molecular weight of 496.6. In addition to the active component, imidocarb dipropionate, the formulation also contains propionic acid (22.34 mg/mL), and water for injection.

INDICATIONS:

For the treatment of dogs with clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

DOSAGE AND ADMINISTRATION:

Use intramuscularly or subcutaneously at a rate of 6.6 mg/kg (3 mg/lb) body weight. Repeat the dose in two (2) weeks, for a total of two (2) treatments.

IMIZOL® DOSING GUIDE 6.6 mg/kg Body Weight

Animal Weight	IMIZOL Dosage
10 lb (4.5 kg)	0.25 mL
20 lb (9.1 kg)	0.50 mL
30 lb (13.6 kg)	0.75 mL
40 lb (18.2 kg)	1.00 mL
60 lb (27.3 kg)	1.50 mL
80 lb (36.4 kg)	2.00 mL
100 lb (45.5 kg)	2.50 mL

WARNING: NOT FOR HUMAN USE. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN THE EVENT OF HUMAN EXPOSURE IMMEDIATELY CALL 303-595-4869, FOR MEDICAL ADVICE FOR HUMANS.

Oncogenesis: Increased incidence of tumors was observed in rats given imidocarb.

PRECAUTION:

MUST NOT BE ADMINISTERED INTRAVENOUSLY. The safety and effectiveness of imidocarb have not been determined in puppies or in breeding, lactating, or pregnant animals. Risk versus benefit should be considered before using this drug in dogs with impaired lung, liver, or kidney function. Do not use this product simultaneously with exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

ADVERSE EFFECTS:

Adverse effects commonly seen are pain during injection and mild cholinergic signs such as salivation, nasal drip, or brief episodes of vomiting. Other effects seen less frequently are panting, restlessness, diarrhea, and mild injection site inflammation lasting one to several days. Rarely, injection site ulceration occurs, but the lesion is not resistant to healing.

If severe cholinergic signs occur, they may be reversed with atropine sulfate.

To report an adverse reaction, product-related problem, or human exposure, please call Merck Animal Health Technical Services at 1-800-224-5318. To obtain a copy of the Material Safety Data Sheet (MSDS), call 1-800-770-8878. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/AnimalVeterinary/SafetyHealth/.

TOXICOLOGY:

IMIZOL solution was administered subcutaneously to four groups of 5 dogs at 2.2, 5.5, 7.7, or 9.9 mg/kg. The treatment was repeated 2 weeks later. There were no effects attributed to IMIZOL on body temperature, body weight, hematology, most clinical chemistries or gross pathology. At 9.9 mg/kg there was a slight increase in serum alanine aminotransferase (ALT, SGPT) and arginine aminotransferase (AST, SGOT) indicative of mild liver injury. Other effects noted were pain on injection, injection site swelling, and vomiting. Two of the injection sites ulcerated but healed readily without complication.

In a 90-day toxicity study, imidocarb was given orally to three groups of 8 dogs at the rate of 5, 20, or 80 mg/kg/day. The target organs of toxicity were liver and intestines. These results may have been influenced by the oral dosing route. In a pharmacokinetic study by Abdullah et al (1984)[1], imidocarb was administered to dogs intravenously at a dose of 4 mg/kg. One of 13 dogs died. The target organs of toxicity in this dog were lungs and kidneys, and some changes were noted in the liver and spleen.

The toxic syndrome involves lethargy, weakness, and anorexia, with possible signs of gastrointestinal, liver, kidney, and lung dysfunction.

PHARMACODYNAMICS:

The pharmacodynamics of imidocarb were studied in various species as described by Rao et al (1980)[2]. The study suggests that there is a potential for adverse reactions mediated by the autonomic nervous system and especially through anticholinesterase mechanisms. Clinical experience in dogs at therapeutic dosages of less than 10 mg/kg body weight given intramuscularly or subcutaneously has established a pattern of adverse reactions. These reactions in descending order of frequency are: salivation, vomiting, and occasionally diarrhea.

HOW SUPPLIED: IMIZOL® solution is packaged in 10 mL glass, sterile, multiple-dose vials.

STORAGE: Store between 2° and 25°C (36° and 77°F). Protect from light.

REFERENCES:

[1]A. S. Abdullah et al, Veterinary Research Communications. 1984;(8):55-59.

[2]K. S. Rao, Indian Veterinary Journal. 1980; 57(4):283-287.

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