Canine Parvovirus Monoclonal Antibody

For Use in Dogs Only

For use by, or under the supervision of, a veterinarian

The product has shown a reasonable expectation of efficacy against mortality for the treatment of canine parvovirus (CPV) in dogs 8 weeks of age or older when administered at 4 days post exposure to CPV-2b to dogs without a prior history of vaccination for CPV. This product license is conditional; efficacy and potency have not been fully demonstrated. Safety has been demonstrated in healthy dogs. For more complete information regarding safety, go to *productdata.aphis.usda.gov.*

CPV causes enteritis in dogs where the incidence of severe illness and death can be very high in susceptible dogs. The disease is most common in puppies as their maternally derived antibodies wane and in older unvaccinated puppies. The product, Canine Parvovirus Monoclonal Antibody, selectively binds and neutralizes canine parvovirus.

Composition:

This product is a sterile liquid containing a chimeric monoclonal antibody (rat variable region, canine constant region) against canine parvovirus (CPV) viral protein 2.

Directions:

The product is supplied and stored frozen at ≤-15°C (≤5°F) and is ready to use once thawed. Thaw at room temperature (~17-25°C) and immediately administer intravenously at a dose of 0.2 ml/kg (0.2 ml/2.2 lb) of the dog's body weight.

Examples of the volume to administer are provided in the table below. If more than one vial is required due to the weight of the dog, draw from each vial into one syringe and administer as a single injection. Vials are single-use, and any remaining product is to be discarded.

Dog's body weight **POUNDS**	Dog's body weight **KILOGRAMS**	Volume to administer
2.2	1	0.2 ml
11	5	1 ml
22	10	2 ml
33	15	3 ml
44	20	4 ml
55	25	5 ml

Efficacy:

Twenty-eight CPV negative purpose bred dogs were intranasally challenged with virulent canine parvovirus type 2b (CPV-2b) at 8 weeks-of-age. All dogs tested positive for CPV in feces (by SNAP test) four days after challenge, with or without clinical signs of canine parvovirus. The same day as testing positive by SNAP test, the dogs were treated intravenously with a single dose (0.2 ml/kg) of the CPV monoclonal product or placebo. Virulent CPV-2b challenge resulted in no mortality of the CPV monoclonal treated dogs (0/21; 0% mortality) compared to the placebo control group (4/7; 57% mortality) during the 14 day observation period.

Safety:

Field safety data analysis of 147 client owned dogs of various breeds, ranging from 6 weeks of age to 15 years and weighing between 0.6 – 59.2 kg (1.3 – 130 lbs), and located in nine separate sites concluded the product is well tolerated when administered to healthy dogs by the intravenous route. No anaphylactic reactions or clinical presentations consistent with anaphylaxis were reported.

Adverse Reactions

The following tables present adverse reactions that were reasonably associated with the use of this product in the clinical field safety trial. Most were mild and recovered within one day. Three dogs took 2-4 days to recover. One dog had continuing site inflammation until study exit (14 days after injection). For more complete information regarding safety and adverse events, see *productdata.aphis.usda.gov*. The most common adverse reactions reported were injection site reactions (4%).

Table 1. Injection Site Reactions

Injection Site Reaction VeDDRA Code	**No. of Dogs Exhibiting Reaction (n=147)**
Erythema	3 (2%)
Inflammation	2 (1%)
Edema	1 (<1%)
Pain	2 (1%)
Total No. of Dogs Affected*	6 (4%)

*Some dogs displayed multiple injection site reactions when affected.

Table 2. Systemic Adverse Reactions

Adverse Reaction VeDDRA Code	**No. of Dogs Exhibiting Reaction (n=147)**
Diarrhea	2 (1%)
Pruritis	1 (<1%)
Total No. of Dogs Affected*	3 (2%)

Precautions:

STORE FROZEN at ≤ -15°C (≤5°F). Single Use. For IV administration only. For use by, or under the supervision of, a veterinarian. Use entire contents after thawed and when first opened, do not refreeze. Do not mix with other products. In case of anaphylactoid reaction, administer epinephrine. This product has not been tested in pregnant animals.

Warnings:

In case of human exposure, contact a physician. Along with active immunity initiated by the naturally occurring CPV infection, the use of this monoclonal antibody as therapeutic treatment may interfere with subsequent CPV vaccination. For advice on CPV vaccination scheduling after use, consult your veterinarian.

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Caution: In the absence of a veterinarian-client-patient relationship, Federal law prohibits the relabeling, repacking, resale, or redistribution of the individual contents of this package.

PRODUCT INFO

BLUE #:	103743Asa
Item Code:	PA103743A
Product Code:	AV6970
Previous Item Code:	PA103743X
Product Name:	Canine Parvovirus Monoclonal Antibody

REVISION CHECK - QO / SO*

REVISION

- TVT completed (if applicable)
- PDF Compare completed (if applicable)
- Proof # is updated and correct
- File name is updated and correct

By/Date		
	SO	JKL 03-MAY-2023
	QO	NA

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PRIMARY CHECK - QO / SO

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- BLUE #, Item Code, Previous Item Code, Product Code and Product Name match approved production component
- Proof # is correct

CONTENT

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- Native file / PDF named correctly

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	SO	NA
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