



Canine Parvovirus Monoclonal Antibody

FAQs

Why is the Canine Parvovirus Monoclonal Antibody under a conditional license?

On the label, it reads “This product license is conditional; efficacy and potency have not been fully demonstrated.”¹ This statement is the standard wording for conditionally licensed products. However, specifically for Canine Parvovirus Monoclonal Antibody (CPMA), this product license is conditional because a validated potency assay has not been fully demonstrated.

What is the efficacy of the Canine Parvovirus Monoclonal Antibody?

CPMA demonstrated 100% efficacy in prevention of mortality associated with Canine Parvovirus (CPV) infection when administered as a *sole therapy* at first test positive of CPV antigen in the feces in the treatment efficacy study.¹ Additionally, CPMA treated dogs had significantly faster times to resolution of vomiting, lethargy and inappetence.²

What is the safety of Canine Parvovirus Monoclonal Antibody? What are the most common side effects of Canine Parvovirus Monoclonal Antibody?

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.¹

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 all possible adverse events, see productdata.aphis.usda.gov. The most common adverse reactions reported were injection site reactions (4%).¹

Table 1. Injection Site Reactions¹

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 Reactions¹

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

Can Canine Parvovirus Monoclonal Antibody be given with other medications?

We know that the treatment of canine parvovirus is multimodal and often includes multiple medications. There are no known drug interactions with CPMA and veterinary medications. In the field safety study in overall healthy dogs, other concomitant medications ranged from dexamethasone SP, diphenhydramine, cetirizine, flea/tick medications, heartworm preventatives, dewormers, anti-anxiety medication,



pain medications, antibiotics, dermatology products, maropitant, enalapril, furosemide, pimobendan.³

In the field safety study, dogs could not receive long acting, systemic steroids or other immunosuppressant drugs within 4 weeks prior to first visit.³

Are there any age restrictions for patients being administered Canine Parvovirus Monoclonal Antibody?

CPMA is labeled for use in dogs 8 weeks of age and older. The dogs in the treatment efficacy study were 8 weeks of age.¹ In the field safety study, the youngest dogs receiving IV CPMA were 6 weeks of age.³ Use of the product under 8 weeks of age is considered off label use, cannot be recommended by Elanco and would be at the veterinarian's discretion.

Are there any contraindications for using Canine Parvovirus Monoclonal Antibody?

There are no contraindications for using Canine Parvovirus Monoclonal Antibody for treatment of canine parvovirus infection.

Why is the product stored frozen?

Typical shelf life for antibodies is 12-18 months so frozen storage provides longer shelf-life. The shelf life of frozen CPMA is 24 months.

How long is canine monoclonal good for after taking it out of the freezer?

Product is intended to be administered as soon as it has thawed.¹ There are no stability studies on extended room temperature exposure for the product.

Can Canine Parvovirus Monoclonal Antibody be re-frozen after it has thawed?

There have been no safety, efficacy or stability studies on re-freezing the product and re-freezing would not be recommended. Any remaining product should be discarded as no studies on re-freezing or prolonged room temperature shelf life have been completed. The label states: Use entire contents after thawed and when first opened, do not refreeze.¹

Does the product need to be shaken before use?

The product should not be shaken. In each study, care was taken that the vials were not shaken either during

or after thawing in the studies. It was mixed with gentle swirling.

What happens if I accidentally give product subcutaneously (SC) or intramuscularly (IM)?

CPMA is labeled for intravenous administration.¹

Administration of CPMA by the SC or IM route is considered off label and cannot be recommended by Elanco. As part of the field safety study of 391 dogs, 244 puppies and dogs received the product subcutaneously. Of the 244 dogs receiving the product SC, injection site pain was seen in 2 dogs and injection site inflammation in 1 dog.³

There are no studies if the product is administered IM.

How long will the Canine Parvovirus Monoclonal Antibody interfere with vaccination?

Currently we do not know how long CPMA will interfere with vaccination. 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 or the Elanco veterinary team.¹

References:

1. Canine Parvovirus Monoclonal Antibody Product Insert
2. Elanco Animal Health. Data on file.
3. Elanco Animal Health. Data on file.

