PrimeMune™

Canine Distemper - Adenovirus Type 2 - Parainfluenza - Parvovirus Vaccine, Modified Live Virus

INDICATIONS

For subcutaneous vaccination of healthy dogs for prevention of disease caused by canine distemper virus, canine adenovirus Type 2 and as an aid in the prevention of disease caused by canine parainfluenza virus and canine parvovirus.

Minimum age for vaccination – 6 weeks, revaccinate at 3–4 week intervals until the dog is 12 weeks of age. Annual revaccination with one dose is recommended.

BENEFITS

• Contains key vaccine antigens including Distemper, Adenovirus Type 2, Parvovirus and Parainfluenza for protection of both puppies six weeks of age or older and adult dogs
• Modified live vaccine provides for high levels of protective immunity
• Contains attenuated type 2 parvovirus
• Approved, registered, and licensed by USDA as meeting or exceeding government standards.
• Easy, subcutaneous administration
• Unique 10 dose package size to meet more specific needs of clinics and professional breeders
• Packaged in clear, nested boxes for easy, convenient storage and inventory
• Color coated stopper retaining rings for easy product identification

PACKAGING

<table>
<thead>
<tr>
<th>LIST NO.</th>
<th>UNIT PACKAGE</th>
<th>CASE SIZE</th>
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<tbody>
<tr>
<td>1PRI001</td>
<td>10 x 1 mL</td>
<td>60 x 10 x 1 Vials of Vaccine</td>
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<tr>
<td></td>
<td>Vials of Vaccine</td>
<td>10 x 1 mL Vials of Diluent</td>
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See reverse side for Administration and Dosage.
Modified live vaccine against canine distemper (CDV), adenovirus Type 2 (CAV-2), parvovirus (CPV-2), parainfluenza (CPIV-2) in dogs.

FOR USE IN HEALTHY DOGS ONLY

Composition – 1 mL:

a) FREEZE-DRIED COMPONENTS:
   - Distemper
   - Adenovirus Type 2
   - Parvovirus
   - Parainfluenza

b) DILUENT: Water for Injection

DRUG FORM: Freeze-dried injection.

IMMUNOLOGICAL PROPERTIES:
After being injected into the body of the vaccinated individual, the antigens present in the vaccine are recognized as extraneous elements and a number of defensive mechanisms in the body are activated (macrophages, opsonins, interleukins, B lymphocytes, etc.), in consequence of which specific antibodies against the antigen determinants contained in the vaccine start to form. The said mechanisms shall prevent from subsequent development of the infection after contagion.

TARGET SPECIES: Dogs.

WITHDRAWAL PERIODS: Not intended for food animals.

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For subcutaneous vaccination of healthy dogs for prevention of disease caused by canine distemper virus, canine adenovirus Type-2 and as an aid in the prevention of disease caused by canine parainfluenza virus and canine parvovirus.

Minimum age for vaccination – 6 weeks, revaccinate at 3–4 week intervals until the dog is 12 weeks of age. Annual revaccination with one dose is recommended.

CONTRAINDICATION: Total pyrexial disease.

INTERACTION:
No information is available on the compatibility of this vaccine with any other vaccine.

RECOMMENDED VACCINATION SCHEDULE: See above.

CANINE AGE: 6–16 weeks.

ANNUAL REVACCINATION:
The vaccination schedule should be specified by the veterinarian depending on the infection situation and the level of the passive immunity obtained due to antibodies in the vaccinated individuals. Annual revaccination is recommended to maintain permanent immunity.

SPECIAL PRECAUTIONS FOR USE:
Only clinically healthy animals in a good nutrition condition should be vaccinated. Possible anti-parasitic treatment should be carried out at least 10 days before the vaccination. The vaccinated animals should not be trained or exercised for one week after the vaccination.

When diluted, the vaccine shall be used immediately.

DOSAGE AND ROUTE OF ADMINISTRATION:
The dose is 1 mL regardless of age, weight and breed of the individual, vaccination may be first performed during the sixth week of age.

Route of administration – subcutaneously, preferably in zone behind the shoulder blade.

ADVERSE EFFECTS: None known.

PACKAGE:
Plastic box – 10 x 1 mL of vaccine and 10 x 1 mL of sterile diluent
The package insert is attached to each package.

STORAGE: Store in a dry and dark place between 2–7°C. Do not use after the expiry date stated on the label. When diluted, the vaccine shall be used immediately.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY:
The packages and any remainders of the preparation are to be disposed of pursuant to the regulations in force. Burn the container and all unused contents.

Manufactured by:
Bioveta, a.s., Komenského 212, Ivanovice na Hané, Czech Republic

Produced for:
Aceto Pharma Corp., 4 Tri Harbor Court, Port Washington, NY, USA 11050

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