



**Company Name:** INTERVET AUSTRALIA PTY LIMITED  
**Product Name:** NOBIVAC DHP CONTINUUM VACCINE  
**eLabel Application No:** DC12-96382723E9  
**APVMA Approval No:** 59043/100594

<b>Label Name:</b>	NOBIVAC DHP CONTINUUM VACCINE
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<b>Signal Headings:</b>	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
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<b>Constituent Statements:</b>	<p>[Vial] Contains live canine distemper virus, canine adenovirus type 2, canine parvovirus</p> <p>[Pack Insert Front] Contains per dose: &gt;4.0 log<sub>10</sub> TCID<sub>50</sub> canine distemper virus, &gt;4.0 log<sub>10</sub> TCID<sub>50</sub> canine adenovirus type 2, &gt;7.0 log<sub>10</sub> TCID<sub>50</sub> canine parvovirus.</p> <p>[Pack Insert back] Each single dose contains at least: 10<sup>4.0</sup> TCID<sub>50</sub> canine distemper virus (CDV) strain Onderstepoort, 10<sup>4.0</sup> TCID<sub>50</sub> canine adenovirus type 2 (CAV2) strain Manhattan LPV3 and 10<sup>7.0</sup> TCID<sub>50</sub> canine parvovirus (CPV) strain 154.</p>
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<b>Claims:</b>	<p>[Pack insert front] Live vaccine to provide protection against canine distemper (CDV), infectious canine hepatitis caused by canine adenovirus type 1 (CAV1), canine parvovirus disease (CPV) and respiratory disease caused by canine adenovirus type 2 (CAV2), and to prevent viral excretion caused by canine parvovirus infection.</p> <p>[Pack insert back] DESCRIPTION: This vaccine contains freeze-dried living attenuated strains of canine distemper virus (CDV) strain Onderstepoort, canine adenovirus type 2 (CAV2) strain Manhattan LPV3 and canine parvovirus (CPV) strain 154, grown in cell-line tissue culture. It is presented as a freeze-dried plug in single dose vials containing not less than 10<sup>4.0</sup> TCID<sub>50</sub> CDV, 10<sup>4.0</sup> TCID<sub>50</sub> CAV2 and 10<sup>7.0</sup> TCID<sub>50</sub> CPV attenuated vaccine virus. Each vial contains a single dose for reconstitution.</p>
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<b>Net Contents:</b>	<p>[Vial] Single dose vial</p> <p>[Pack insert front] 10, 20, 25 &amp; 50 x single dose vials (1mL after reconstitution)</p>
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<b>Directions for Use:</b>	<p>[Vial and Pack insert front]  <b>READ THE REVERSE SIDE OF THE PACK INSERT BEFORE USING THIS PRODUCT.</b></p> <p>[Pack insert back]  <b>DIRECTIONS FOR USE</b>  <b>USE ALL PRODUCT WITHIN 30 MINUTES OF RECONSTITUTION.</b></p>
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<b>Precautions:</b>	<p>[Pack insert back]  <b>MANDATORY WARNINGS:</b>  Only healthy dogs should be vaccinated and an adequate clinical examination should be made prior to inoculation.  Sterile equipment should be used for administration, but avoid contamination of vaccine with traces of disinfectant or spirit.</p>
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<b>Side Effects:</b>	<p>[Pack insert back]  Occasionally a mild anaphylactic type hypersensitivity reaction may occur after vaccination, as is possible after inoculation of any foreign protein. Such types of reaction are in most cases self-limiting but may occasionally need veterinary intervention.</p>
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<b>Dosage and Administration:</b>	<p>[Pack insert back]  <b>DOSAGE AND ADMINISTRATION:</b>  The contents of one vial of reconstituted vaccine should be injected subcutaneously. Reconstitute immediately prior to use by the addition of 1.0 mL of Nobivac® Bb/Pi or sterile water for injection or sterile phosphate buffer. Concurrent vaccination of Nobivac® KC and Nobivac® DHP vaccines has been shown to be safe and effective.</p>
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<b>General Directions:</b>	<p>[Pack insert back]  <b>DESCRIPTION:</b>  This vaccine contains freeze-dried living attenuated strains of canine distemper virus (CDV) strain Onderstepoort, canine adenovirus type 2 (CAV2) strain Manhattan LPV3 and canine parvovirus (CPV) strain 154, grown in cell-line tissue culture. It is presented as a freeze-dried plug in single dose vials containing not less than 10<sup>4.0</sup> TCID<sub>50</sub> CDV, 10<sup>4.0</sup> TCID<sub>50</sub> CAV2 and 10<sup>7.0</sup> TCID<sub>50</sub> CPV attenuated vaccine virus. Each vial contains a single dose for reconstitution.</p> <p><b>GENERAL DIRECTIONS:</b>  The vaccination program consists of a single vaccination from the age of 10 weeks. If protection of younger puppies is desired, vaccination can be initiated from 6 weeks of age, but revaccination must then be made 2 to 4 weeks later with the final vaccination at 10 weeks of age or more. It is recommended that puppies be boosted 12 months after the primary course; thereafter dogs need only be revaccinated against distemper, hepatitis and parvovirus every 3 years.</p> <p>Vaccination program:  Puppies:  Recommended program for pups where vaccination is started at 6-8 weeks:  Age 6-8 weeks Nobivac® DHP  Age 10 weeks Nobivac® DHP  Where vaccination commences at 10 weeks or beyond: Nobivac® DHP  Booster vaccination  1st booster, 12 months after primary vaccination Nobivac® DHP  2nd booster, 3 years after 1st booster Nobivac® DHP  Subsequent boosters, every 3 years Nobivac® DHP</p> <p>Adult Dogs:  Regardless of vaccination history, a single vaccination with Nobivac® DHP will provide at least three years protection against distemper, hepatitis and parvovirus.</p>
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	<p>This product has been assessed as providing at least 36 months protection. Many factors influence the effectiveness of vaccination and the need for revaccination. The vaccination program for an individual animal should be determined within a veterinarian-client-patient relationship, taking all these factors into account.</p> <p>Booster vaccination Subsequent boosters, every 3 years Nobivac® DHP</p> <p><b>FURTHER INFORMATION:</b> Experience has shown that the maternal antibody status of pups within a litter varies greatly and reliance should not be placed on serological examination of the bitch alone.</p> <p><b>OVERDOSAGE:</b> No particular signs at 10-fold overdose.</p>
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<b>First Aid Instructions:</b>	<p>[Pack insert back] <b>FIRST AID</b> If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.</p>
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<b>First Aid Warnings:</b>	
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<b>Additional User Safety:</b>	<p>[Pack insert back] Additional User Safety Take care to avoid self-injection.</p>
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<b>Disposal:</b>	<p>[Pack insert back] <b>DISPOSAL:</b> Discarded vials should immediately be placed in a designated and appropriately labelled 'biologicals' container. If this option is not available, bury the vial/container below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and roots. Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container.</p>
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<b>Storage:</b>	<p>[Vial] Store between 2oC and 8oC (Refrigerate. Do not freeze). Protect from light.</p> <p>[Pack insert back] <b>STORAGE:</b> Store between 2oC and 8oC (Refrigerate. Do not freeze). Protect from light.</p>
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