

Virbac (Australia) Pty Limited		Page 1 of 2
Product Name:	Canigen <sup>®</sup> KC Bivalent inactivated vaccine for dogs	
APVMA Number:	45198/61114	
Version Date:	13 December 2013	
Pack sizes:	10 x 1mL single dose vials	

## TEMPLATE FOR RELEVANT LABEL PARTICULARS (RLPs) (*Veterinary Products*)

Select appropriate:

New Product (include all applicable RLPs) OR

Variation (highlight instructions that are being varied). Approval no. of label being varied: 45198/0506

Signal heading:	<b>FOR ANIMAL TREATMENT ONLY</b>
Product name:	<b>Canigen<sup>®</sup> KC Bivalent inactivated vaccine for dogs</b>
Active constituent/s:	Each single dose vial contains (minimum titres): - purified inactivated <i>Bordetella bronchiseptica</i> antigen.....0.05 µg - inactivated canine parainfluenza virus.....10 <sup>6</sup> TCID <sub>50</sub> - aluminium hydroxide (adjuvant).....3 mg
Statement of claims:	<b>For active immunisation of dogs against <i>Bordetella bronchiseptica</i> and canine parainfluenza virus.</b>
Net contents:	10 x 1 mL single dose vials
Directions for Use Heading:	<b>READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT DIRECTIONS FOR USE:</b>
Restrains:	<b>N/A</b>
Contraindications:	<b>N/A</b>
Precautions:	<b>Do not vaccinate dogs receiving corticosteroids. Do not vaccinate pregnant bitches.</b>
Side effects:	A local reaction with swelling or pain at the injection site may uncommonly be observed. Some dogs may show transient post-vaccination reaction such pain, lethargy, vomiting, and/or anorexia. Rarely, an animal may show a systemic hypersensitivity reaction. Allergic reactions such as anaphylaxis occur very rarely and may require appropriate treatment.
Dosage & administration:	<b>Only healthy dogs possessing normal temperatures should be vaccinated.</b>  <b>Under normal circumstances:</b> Primary vaccination: inject subcutaneously or intramuscularly 2 doses of vaccine at an interval of 1 month to dogs 6 weeks of age or over. Canigen KC <sup>®</sup> can be used as a diluent for Canigen <sup>®</sup> DH <sub>A2</sub> P Trivalent Living Vaccine. An annual booster is recommended. Due to the interference of maternal antibodies with active immunisation, protection of young puppies can be difficult, especially in infected kennels.

Approved  
RTP



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	<p>Epidemiological conditions and likely persistence of maternal antibodies (e.g. antibody titres of the mother, age of weaning) can thus influence the individual response of any given puppy.</p> <p><b>Under severe infectious risk:</b></p> <p>Susceptible puppies may benefit from an early start of the vaccination program (6 weeks of age). Vaccination at 2 to 3 week intervals through until 16 weeks of age may also be appropriate in high risk situations.</p>
General directions:	Because tracheobronchitis can be due to many different agents (multifactorial disease), prevention of all cases can be difficult, when using this vaccine only. Vaccines containing other antigens might be necessary.
Withholding Period/s:	<b>N/A</b>
Trade Advice:	<b>N/A</b>
Safety Directions:	<b>N/A</b>
First Aid:	If poisoning occurs, contact a doctor or Poisons Information Centre, phone Australia 13 11 26.
Additional user safety:	<p>Take Care to Avoid Self-Injection.</p> <p>In the event of self-administration, seek medical attention <u>if you are concerned</u>, show the package leaflet or the label, to the Medical Practitioner.</p>
Environmental statements:	<b>N/A</b>
Disposal:	Dispose of empty containers and outer packaging by wrapping with paper and putting in garbage. Discarded needles/sharps should immediately be placed in a designated and appropriately labelled "sharps" container. Discarded vials should immediately be placed in a designated and appropriately labelled "biologicals" container. If this option is not available, bury the vial below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and roots.
Storage:	Store between 2°C and 8°C (Refrigerate. Do not freeze). Protect from light.
Name & address:	<p><b>Virbac (Australia) Pty Limited</b></p> <p><b>361 Horsley Rd Milperra NSW 2214</b></p>

The following is for APVMA use only:

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