RLP
Approved

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: **[APVMA No. 61447/ATS No. 49981]**

Signal heading:	**FOR ANIMAL TREATMENT ONLY**
Product name:	**COOPERS® BOVILIS® ROTAVEC CORONA CALF SCOURS VACCINE**
Active constituent/s:	**ACTIVE CONSTITUENTS:** **Potency Units:** A multiple antigen product which includes cell-free extract of K99 pilus type of *Escherichia coli* ≥1 RP unit Bovine Coronavirus (inactivated), Type 1 (mebus-like) and Type 3 ≥1 RP unit Bovine Rotavirus (inactivated), Type G6 and Type G10 ≥1 RP unit *Clostridium perfringens* Type C toxoid 10.0 iu/mL *Clostridium perfringens* Type D toxoid 2.0 iu/mL CONTAINS: 0.1 g/L thiomersal
Statement of claims:	Recommended for use in healthy pregnant heifers and cows as an aid in the prevention of neonatal calf diarrhoea by enterotoxigenic *E. coli* pilus type K99, bovine rotaviruses G6 and G10, neonatal enterotoxemia caused by *C. perfringens* Types C and D, and as an aid in the control of neonatal calf diarrhoea caused by bovine coronaviruses. For the active immunisation of pregnant cows and heifers to raise colostral antibodies against bovine rotavirus and coronavirus, enterotoxigenic *E. coli* pilus type K99 and neonatal enterotoxemia caused by *C. perfringens* Types C and D. Calves fed colostrum from vaccinated cows during the first four days of life, will receive antibodies that have been demonstrated to aid the prevention of neonatal calf diarrhoea caused by enterotoxigenic *E. coli* pilus type K99, bovine rotaviruses, enterotoxemia caused by *C. perfringens* Types C and D, and to aid in the control of neonatal calf diarrhoea caused by bovine coronaviruses. In addition calves exposed to bovine rotavirus and coronavirus disease were shown to shed less virus than unvaccinated controls thereby reducing environmental exposure. In the face of heavy challenge colostrum feeding should be extended beyond 4 days.
Net contents:	**20mL (10 Doses)** **100mL (50 Doses)**
Directions for Use Heading:	**READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT.** **DIRECTIONS FOR USE** **Shake contents before use.** **Opened bottles should be used within 12 hours.**
Restraints:	Not applicable

Contraindications:	Not applicable

Precautions:	Transient local reaction may occur at the injection site. Use may lead to development of lumps at the injection site which may persist for several weeks. Compatibility studies with concurrent use of other veterinary products were not performed.
Side Effects:	Not applicable.
Dosage & Administration:	**Dose and Administration:** Using aseptic technique, inject healthy pregnant cattle with 2mL **SUBCUTANEOUSLY** (under the skin) on the side of the neck. For initial vaccination give 10-12 weeks before expected calving, and repeat 4-6 weeks after initial vaccination (ie. 4-6 weeks before calving). An annual booster vaccination should be given 4-6 weeks before each subsequent calving. Protection of calves depends on the physical presence of colostrum antibodies (from vaccinated cows) within the gut for the first few weeks of life until calves develop their own immunity. Thus it is essential to ensure adequate colostrum feeding to maximise the efficacy of vaccination. All calves must receive adequate colostrum from their dams within 6 hours of birth. Suckled calves should receive adequate colostrum naturally by feeding from vaccinated cows. In the dairy herd colostrum from the first 6 - 8 milkings of vaccinated cows should be pooled. Ideally calves should be fed 3-4 litres (10% bodyweight) within the first 24 hours of life. Calves will benefit from ongoing colostrum feeding. In general, pooled stored colostrum may be stored below 20 °C but should be used as soon as possible as immunoglobulin levels may fall by up to 50% after storage for 28 days. Where possible, storage at 4 °C is recommended. Optimal results will be obtained if a whole herd cow vaccination policy is adopted. This will ensure that in calves the level of infection and consequent virus excretion is kept to a minimum and the overall level of disease challenge on the farm is minimised. This vaccine is safe for use in pregnant cows and heifers. It is not recommended for use in young calves. Compatibility studies supporting the concurrent use of this vaccine and other veterinary products have not been performed. **CAUTION: AVOID CARCASS DAMAGE:** **1.** Sterilise needles by boiling before use. Flush cooled boiled water through vaccinator. Avoid use of strong disinfectants on needles and vaccinator. **2.** Maintain maximum cleanliness at all times. **3.** Keep needles sharp and clean. Replace frequently **4.** Use needles of appropriate gauge and length. 15mm x 16 Gauge needles are recommended. **5.** As far as possible avoid injection of animals in wet weather or under dusty conditions. **6.** This product should be injected subcutaneously (under the skin) on the side of the

	neck.
General Directions:	**THE DISEASE:** Calf diarrhoea is a complex disease of which rotavirus, coronavirus and enterotoxigenic *E. Coli*, are three of the most important causal agents in calves in the first few weeks of life. *Clostridium perfringens* enterotoxaemia less frequently causes disease and mortality in young calves. Coopers BOVILIS Rotavec Corona Calf Scours Vaccine will aid in protecting against disease caused by rotavirus G6 and G10, coronavirus, *E. Coli* or *Clostridium perfringens* Types C and D, where these are the causative aetiological agents. Coopers BOVILIS Rotavec Corona Calf Scours Vaccine works through stimulating antibodies in the vaccinated dam, which pass via the colostrum to the calf, where the antibodies act in the calf's intestinal lumen to prevent infection by the causative pathogens. As the level of passive protection induced by the vaccine is not absolute, coronavirus and rotavirus infections may occur in calves from vaccinated dams- but will be contained whilst the calf is mounting its own active immune response against the viruses. Onset of Immunity: Passive protection against these diseases will commence from the start of colostrum feeding in the neonatal period. Ongoing calf protection depends on a number of factors beyond dam vaccination, including quantity and timing of colostrum absorption, ongoing environmental exposure, and any concurrent infections.
Withholding Period/s:	**WITHHOLDING PERIOD: NIL.**
Trade Advice:	**TRADE ADVICE:** Export slaughter interval (ESI). Not required.
Safety Directions:	Not applicable.
First Aid:	If poisoning occurs, contact a doctor or Poisons Information Centre. *Phone Australia 131 126.* Additional information is listed in the Material Safety Data Sheet.
Additional User Safety:	**User Safety and First Aid Information** Extreme caution should be used when injecting oil emulsion vaccines to avoid injecting yourself. Accidental self-inoculation may cause inflammatory reactions or allergic response which requires correct medical management. Medical advice should be sought as soon as possible in the event of self-inoculation. Keep out of reach of children. **Additional information is listed in the material safety data sheet.**
Environmental Statements:	Not applicable.
Disposal:	**DISPOSE** of empty containers and outer packaging by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled "sharps" container. The container should be of a type to reduce the possibility of injury to handlers during collection and disposal. Incineration is the preferred method of disposal, otherwise "sharps" should be buried at a suitable site, such as an on-farm chemical disposal pit located away from watercourses.
Storage:	**Store** at 2 to 8°C (Refrigerate DO NOT Freeze). **KEEP OUT OF REACH OF CHILDREN.**

APVMA Approval No.	**61447/59194**
Batch and Expiry	**Batch No.** **Expiry Date**
Name & address:	**COOPERS ANIMAL HEALTH** A division of Intervet Australia Pty Limited 91-105 Harpin Street, Bendigo East VIC 3550

The following is for APVMA use only:

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