



RLP  
Approved

COOPERS TASVAX 5IN1 VACCINE FOR SHEEP, CATTLE AND GOATS - 46582

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:...46582/PACK SIZE/0707

Signal heading:	<b>FOR ANIMAL TREATMENT ONLY</b>														
Product name:	COOPERS® Tasvax® 5in1 Vaccine for Sheep, Cattle and Goats														
Active constituent/s:	<table><thead><tr><th></th><th>Potency Units:</th></tr></thead><tbody><tr><td><i>Clostridium perfringens</i> Type D toxoid</td><td>5.0 U/mL</td></tr><tr><td><i>Clostridium chauvoei</i> toxoid and inactivated cells</td><td>Meets Ph.Eur.</td></tr><tr><td><i>Clostridium septicum</i> toxoid</td><td>2.5 U/mL</td></tr><tr><td><i>Clostridium novyi</i> Type B toxoid and inactivated cells</td><td>3.5 U/mL</td></tr><tr><td><i>Clostridium tetani</i> toxoid</td><td>2.5 U/mL</td></tr><tr><td colspan="2">Contains 0.015 mg/mL thiomersal as preservative.</td></tr></tbody></table>		Potency Units:	<i>Clostridium perfringens</i> Type D toxoid	5.0 U/mL	<i>Clostridium chauvoei</i> toxoid and inactivated cells	Meets Ph.Eur.	<i>Clostridium septicum</i> toxoid	2.5 U/mL	<i>Clostridium novyi</i> Type B toxoid and inactivated cells	3.5 U/mL	<i>Clostridium tetani</i> toxoid	2.5 U/mL	Contains 0.015 mg/mL thiomersal as preservative.	
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Statement of claims	<p>For the active immunisation against Pulpy Kidney, Blackleg, Malignant Oedema, Black Disease, Swelled head in rams and Tetanus in sheep, cattle and goats.</p> <p>CLOSTRIDIAL VACCINE For the active immunisation against diseases caused by:</p> <ul style="list-style-type: none"><li>● Pulpy Kidney, Enterotoxaemia (<i>Clostridium perfringens</i> Type D)</li><li>● Blackleg (<i>Clostridium chauvoei</i>)</li><li>● Malignant Oedema (<i>Clostridium septicum</i>)</li><li>● Black Disease, Swelled head in rams (<i>Clostridium novyi</i> Type B)</li><li>● Tetanus (<i>Clostridium tetani</i>)</li></ul> <p>In sheep, cattle and goats.</p> <p>Primary course of 2 vaccinations 4-6 weeks apart.</p> <p>Full protection develops within 14 days from the second dose.</p> <p>Studies have shown duration of immunity of 12 months is achieved by following the recommended vaccination program.</p> <p>In areas where the risk from <i>C. novyi</i> type B (Black Disease, Swelled head in rams) is high, seasonal boosters may be required.</p>														
Net contents:	100 mL, 250 mL, 500 mL, 1L														
Directions for Use Heading:	<p><b>READ THE ENCLOSED LEAFLET BEFORE USING THIS PRODUCT</b></p> <p><b>DIRECTIONS FOR USE</b></p> <p>Shake contents before use. USE ALL PRODUCT WITHIN 24 HOURS OF OPENING.</p>														
Restraints:															
Contraindications:															
Precautions:															
Side effects:															

Dosage & administration:	<p><b>DOSAGE AND ADMINISTRATION:</b></p> <p><b>Dose:</b></p> <p>Sheep, lambs and goats: 2mL by subcutaneous injection (under the skin).</p> <p>Cattle: 4 mL by subcutaneous injection.</p> <p><b>Vaccination Programme</b></p> <ul style="list-style-type: none"> <li>• The primary course of immunisation consists of two injections, 4-6 weeks apart.</li> <li>• Vaccinate sheep, goats and cattle from 8 weeks of age</li> <li>• An annual booster vaccination is required, not more than twelve months following the primary course.</li> <li>• Vaccinations should be completed at least two weeks before maximum immunity is required. This may be either a period of risk or in pregnant animals prior to parturition.</li> <li>• Maximum protection is not achieved until the second dose is given.</li> <li>• Previously sensitised ewes/cows should be injected 2-3 weeks before parturition is due to commence.</li> <li>• If the vaccination status of the dam is unknown or she has not been vaccinated in pregnancy it is recommended that the calf/lamb/kid receives the primary vaccination prior to marking.</li> </ul> <p><b>SHEEP</b></p> <p><b>a) Rams:</b> Rams not previously vaccinated should be vaccinated twice at intervals of 4- 6 weeks. An annual booster should be given.</p> <p><b>b) Ewes:</b> Ewes not previously vaccinated should be vaccinated twice 4-6 weeks apart. The second shot should be timed to be given 2-3 weeks prior to lambing. This will protect lambs until approximately 8-10 weeks of age. If ewes have been previously vaccinated correctly against those diseases for which protection is required, then only the pre-lambing vaccination is required.</p> <p><b>c) Lambs:</b> Lambs born to vaccinated ewes should be vaccinated at marking and again after an interval of 4-6 weeks. Lambs born to unvaccinated ewes should be vaccinated as soon as possible and a second shot given at least 4-6 weeks later. The selenium containing vaccine may be used for the 4-6 week vaccination.</p> <p><b>CATTLE</b></p> <p><b>a) Bulls:</b> Bulls not previously vaccinated should be vaccinated twice at intervals of 4- 6 weeks. An annual booster should be given.</p> <p><b>b) Cows:</b> Cows not previously vaccinated should be vaccinated at joining and again 2-3 weeks prior to calving. This will protect the calves for the first 8-10 weeks of age. Annual boosters will be required for full protection against diseases such as Pulpy Kidney, Blackleg, Black Disease and Malignant Oedema.</p> <p><b>c) Calves:</b> Calves should be vaccinated at about 2 months of age, with a second vaccination at least 4- 6 weeks later.</p> <p><b>GOATS</b></p> <p><b>a) Bucks:</b> Bucks not previously vaccinated should be vaccinated twice at intervals of 4- 6 weeks. Boosters will be required at 4-6 monthly intervals in most instances.</p> <p><b>b) Does:</b> Does not previously vaccinated should be vaccinated at joining and again 2-3 weeks prior to kidding. This will protect the kids until approximately 8-10 weeks of age. Boosters will be required every 4-6 months in most instances, with one of these boosters being given 2-3 weeks prior to subsequent kiddings.</p>
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	<p><b>c) Kids:</b> Kids born to vaccinated does should be vaccinated at marking and again 4- 6 weeks later. Kids born to unvaccinated does should be vaccinated as soon as possible and again 4- 6 weeks later. Boosters will be required every 4-6 months in most instances.</p> <p><b>VACCINATION PROCEDURE</b></p> <p><b>CAUTION: AVOID CARCASS DAMAGE:</b></p> <ol style="list-style-type: none"> <li>1. Sterilise needles by boiling for at least ten minutes before use. Flush cooled boiled water through vaccinator. Avoid use of strong disinfectants on needles and vaccinator.</li> <li>2. Maintain maximum cleanliness at all times.</li> <li>3. Keep needles sharp and clean. Change needles frequently (every 20-30 animals). Use short needles. Recommended maximum sizes 15mm x 18 gauge for sheep and goats; 15mm x 16 gauge for cattle.</li> <li>4. Check that the equipment is functioning properly and that it is delivering the correct dose.</li> <li>5. As far as possible avoid injection of animals in wet weather or under dusty conditions.</li> <li>6. Inject only under the skin and not into the muscle, by raising a fold of skin and injecting the dose under the raised skin – <b>NOT INTO IT.</b></li> <li>7. Cattle, sheep, goats should be injected high on the side of the neck, behind the ear.</li> </ol> <p><b>Do not expose directly to heat and light during use. The use of an insulated container is recommended during the day to protect the vaccine. If it is to be hung beside the race, ensure it is on the shady side.</b></p>
General directions:	<p>Coopers Tasvax 5in1 Vaccine will be adversely affected by exposure to heat and light and by freezing.</p> <p>Coopers Tasvax 5in1 Vaccine has been filtered and incorporates an adjuvant to enhance development of protection with minimum risk of damage at the site of vaccination.</p> <p><b>THE DISEASES</b></p> <p>Obtain veterinary advice for accurate diagnosis, and then use an appropriate vaccination program.</p> <p><b>BLACK DISEASE</b></p> <p>Black disease is generally seasonal in appearance and is caused by infection with <i>Clostridium novyi</i> Type B. Black disease is an acute infectious disease of widespread occurrence, especially in areas where liver fluke are prevalent. Bacterial spores survive in the soil or in the livers of sheep. Where damage has occurred in the liver due to fluke invasion, the bacteria grow rapidly and in doing so produce a powerful and deadly toxin. Animals affected with Black Disease will suddenly lie down and die, apparently painlessly and without warning. The only method of prevention of Black Disease losses where fluke is prevalent is by vaccination</p> <p><b>N.B.</b> Treatment for liver fluke and measures to control the snails which act as the intermediate host to the liver fluke should also be carried out.</p> <p><b>SWELLED-HEAD IN RAMS</b></p> <p>Swelled head is an acute disease caused by <i>Clostridium novyi</i> Type B. The disease is characterized by an edematous swelling of the head, face, and neck of young rams. The infection is initiated in young rams by fighting or continual butting of one another. Annual re-vaccination is advised for all rams, prior to</p>

	<p>joining.</p> <p><b>BLACKLEG/MALIGNANT OEDEMA</b></p> <p>(both sometimes called Blood Poisoning)</p> <p>Blackleg/Malignant Oedema is caused by an infection with <i>Clostridium chauvoei</i> and/or <i>Clostridium septicum</i>. These organisms contaminate the soil. Young stock, thriving on good pasture, are very susceptible. The disease occurs commonly after handling stock (eg. yarding for weaning or marking) or after injuries caused by shearing, marking, dipping lambing etc. Some symptoms are rapid breathing, depression, lameness in one or more legs. The skin becomes discoloured and when touched may impart a crackling feeling due to the presence of gas in the tissue. In all areas where this disease occurs or is likely to occur, regular vaccination programs should be adopted.</p> <p><b>PULPY KIDNEY</b></p> <p>(Enterotoxaemia)</p> <p>Pulpy Kidney is caused by infection with <i>Clostridium perfringens</i> Type D. The bacteria causing this disease are normally present in the bowels of healthy sheep, cattle and goats. The bacteria, given favourable conditions (such as a change from dry to lush feed or lush to dry feed), grows rapidly and in so doing, produces a very strong toxin, which is quickly fatal. Symptoms in young stock are convulsions, clamping of the jaws, rolling eyes and the head drawn backward. In adult animals, where the onset of the disease is slower, the symptoms are not as violent. A staggering gait may be noticed and some scouring is apparent just before death. Deaths occur suddenly, therefore protection by vaccination is the only sure method of prevention. Annual revaccination is advisable on heavily infected properties.</p> <p>The disease is also the major killer of goats and close attention to a good vaccination program is essential if losses are to be kept to a minimum.</p> <p><b>TETANUS</b></p> <p>Tetanus is caused by infection with <i>Clostridium tetani</i>. Bacterial spores are present in soil and manure and can survive for many years. The spores enter the body at any point where there is a wound and upon entry quickly grow, producing a deadly toxin which affects the nervous system. There is a gradual onset of stiffness followed by tetanic spasm of muscles. The signs are evident in the gait, eyelids, ears, nostrils and tails. The muscles do not relax completely between spasms.</p>
Withholding Period/s:	<b>Zero (0) days.</b>
Trade Advice:	<b>EXPORT SLAUGHTER INTERVAL (ESI): Zero (0) days.</b>
Safety Directions:	
First Aid:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.
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 label to the Medical Practitioner.</p> <p>Additional information is listed in the Material Safety Data Sheet.</p>
Environmental statements:	
Disposal:	<b>Dispose</b> of empty container by wrapping with paper and putting in garbage.
Storage:	<b>Store</b> at 2 to 8°C (Refrigerate Do Not Freeze). Protect from light. <b>Keep out of</b>

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	reach of children.
Batch & Expiry:	REFER TO BATCH AND EXPIRY ON TOP PANEL (B) EXP.
Name & address:	COOPERS ANIMAL HEALTH Intervet Australia Pty Limited 91-105 Harpin Street, Bendigo East VIC 3550

The following is for APVMA use only:

APVMA approval no.	APVMA No: 46582/63280
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