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. 36308/100mL/0210]**

Signal heading:	**PRESCRIPTION ANIMAL REMEDY** **KEEP OUT OF REACH OF CHILDREN** **FOR ANIMAL TREATMENT ONLY**
Product name:	**Trivetrin® Injection**
Active constituent/s:	**TRIMETHOPRIM 40 mg/mL** **SULFADOXINE 200 mg/mL**
Statement of claims: RLP Approved DISPLAYED BY INFOPEST	**For the treatment of infections caused by organisms sensitive to trimethoprim and sulfadoxine in cattle, sheep, pigs, horses, cats and dogs.** **Trivetrin Injection** contains 40 mg/mL trimethoprim, a synthetic antibacterial developed in the Wellcome Research Laboratories, and 200 mg/mL sulfadoxine, a long-acting sulfonamide. Trivetrin is effective against most Gram-positive and Gram-negative bacteria. The two components of **Trivetrin** produce a sequential double blockade of bacterial metabolism giving a level of activity many times greater than that obtained from either drug alone. **INDICATIONS:** **Trivetrin Injection** is indicated for the systemic treatment of: **Respiratory infections** of bacterial origin including pneumonia, bronchitis and secondary bacterial infections following virus pneumonia. **Urogenital tract infections** including cystitis, vaginitis, urethritis, nephritis and metritis. **Alimentary tract infections** including *E. coli* infections and salmonellosis. Post-operative and most post-parturient uses, wound infections and septicaemias. **Trivetrin** is active **in vitro** against Gram-positive and Gram-negative organisms including *Actinomyces* spp., *Bacillus anthracis*, *Bordetella* spp., *Brucella* spp., *Clostridium* spp., *Corynebacterium* spp., *Escherichia coli*, *Haemophilus* spp., *Klebsiella* spp., *Shigella* spp., *Staphylococci*, *Streptococci*, *Pasteurella* spp., *Salmonella* spp., *Fusiformis* spp., and *Campylobacter* spp. **Note** *Erysipelothrix*, *Leptospira* and *Pseudomonas* organisms are not sensitive to **Trivetrin**, nor is *Mycobacterium tuberculosis*.
Net contents:	**100mL**
Directions for Use Heading:	**READ THE ACCOMPANYING LEAFLET BEFORE USING THIS PRODUCT.** **DIRECTIONS FOR USE:**
Restraints:	Not applicable
Contraindications:	Contraindicated prior to and after treatment with sedatives/anaesthetics when horse is recumbent. In addition, the subcutaneous and intramuscular routes are not recommended in horses. The use of the intravenous route in cats for cases of acute infection is contraindicated.
Precautions:	Not applicable.
Side Effects:	**Trivetrin** is well tolerated. Very occasionally effects at the site of injection are encountered. These are seen as local irritating swellings of a temporary nature.
Dosage & Administration:	Use unused portion within 28 days of first broaching. **SHAKE WELL BEFORE USE.** **DOSE RATE:**

	Cattle, Pigs, Sheep and Horses - 1 mL per 15kg bodyweight daily. In cases of severe infection the dose may be increased to 1 mL per 10kg bodyweight daily. Animals may be treated by injection alone or the initial injection followed by daily administration of one of the oral Tribrissen formulations. **Dogs and Cats - Trivetrin** may be used to initiate a course of treatment with Tribrissen 20 or 80 Tablets, the dose being a single injection of 1 mL per 15kg bodyweight if it is to be followed by the first tablet within 12 hours. If the administration of the first tablet is to be delayed until the day following injection then the dose is 1 mL per 8kg bodyweight. Sulfadoxine is "long-acting" in cats and dogs, and while no consequential toxic effects have been reported, very high blood levels of sulfadoxine can follow repeated daily injections of **Trivetrin** in these species. Tribrissen tablets containing sulfadiazine are however, suitable for repeated dosing. 1 mL of **Trivetrin** contains 40 mg trimethoprim and 200 mg sulfadoxine. Refer to leaflet for appropriate routes of administration in the various species. **ADMINISTRATION:** Intramuscular Injection is recommended for cattle, sheep and pigs (for pigs the usual site behind the ear is recommended). **Trivetrin** is suitable for use in horses but should be administered **BY SLOW INTRAVENOUS INJECTION ONLY**. The subcutaneous and intramuscular routes are not recommended. Dogs should be injected subcutaneously in the dorsal region or "scruff" of the neck. Subcutaneous injections at other sites or intramuscular injections are not recommended since pain reactions have been observed in some cases. Cats should be injected subcutaneously or intramuscularly. Where necessary, for instance in cases of acute infection, **Trivetrin** may be administered to all the above species intravenously with the exception of cats. **Any variation by the prescribing veterinarian to the approved dose, frequency, duration, route, disease or target species may result in the need to extend the approved withholding period.**
General Directions:	**Trivetrin Injection** is supplied in bottles of 100 mL.
Withholding Period/s: Carton/Leaflet: Label (shortened):	**MEAT: (CATTLE, SHEEP, PIGS): DO NOT USE less than 14 days before slaughter for human consumption. (HORSES): DO NOT USE less than 28 days before slaughter for human consumption.** **MILK: Milk collected from cows and ewes within 36 hours (3 milkings) following a single treatment or 72 hours (6 milkings) following the last of multiple treatments, MUST NOT BE USED for human consumption or processing. This milk should not be fed to bobby calves.** **MEAT: DO NOT USE less than 14 days (cattle, sheep, pigs) 28 days (horses) before slaughter for human consumption. MILK: Milk collected from cows and ewes within 36 hours (3 milkings) following a single treatment or 72 hours (6 milkings) following the last of multiple treatments, MUST NOT BE USED for human consumption or processing. This milk should not be fed to bobby calves.**
Trade Advice:	**EXPORT SLAUGHTER INTERVAL (ESI):** This product does not have an ESI established. For advice on the ESI contact Jurox Pty Ltd on 1800 023 312 before using this product.
Safety Directions:	Not applicable.
First Aid:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
Additional User	Not applicable.

Safety:	
Environmental Statements:	Not applicable.
Disposal:	**Dispose** of empty container by wrapping with paper and putting in garbage.
Storage:	**Store** below 25°C (Air Conditioning). Use unused portion within 28 days of first broaching. PROTECT FROM LIGHT.
Batch and Expiry Immediate Container/Carton:	Ⓑ **EXP** See base for batch and expiry
Name & address:	Made in Australia by: Jurox Pty Limited 85 Gardiner Road Rutherford, NSW 2320 Australia Infoline: 1800 023 912 Under licence from: Intervet/MSD Animal Health

The following is for APVMA use only:

APVMA approval no.	**36308/60465**