RLP
APPROVED

Product Name: Coopers Bovilis MH Single-Shot RTU READY-TO-USE MH VACCINE FOR CATTLE
APVMA Approval No: 92022/134188

Label Name:	Coopers Bovilis MH Single-Shot RTU READY-TO-USE MH VACCINE FOR CATTLE

Signal Headings:	FOR ANIMAL TREATMENT ONLY

Constituent Statements:	ACTIVE CONSTITUENTS Inactivated Mannheimia haemolytica Strain x 387 (Leucotoxin producing) ≥1 x 10^7 orgs/mL Strain x 332 ≥1 x 10^8 orgs/mL

Claims:	A ready-to-use, fast-acting, single-shot vaccine for the protection of cattle against Bovine Respiratory Disease (BRD) caused by Mannheimia haemolytica (MH). Significant immunological response achieved within 7 days after a single dose vaccination and remains high for at least 180 days (25 weeks).

Net Contents:	100 mL (50 doses) 250 mL (125 doses) 500 mL (250 doses)

Directions for Use:	

Restraints:	

Contraindications:	

Precautions:	Interactions: No information is available on the safety and efficacy from the concurrent use of the vaccine with any other. This vaccine is safe for use in pregnant cattle during the second and third trimester of pregnancy. Safety in the first trimester of pregnancy has not been determined.

Side Effects:	Vaccination can cause a swelling at the site of injection and could last for up to 21 days. The area of local reaction is generally less than 10 cm in diameter but will eventually

	resolve. A rise in internal body temperature may occur, returning to normal within 24-48 hours post-vaccination. This may result in some temporary loss of appetite.

Dosage and Administration:	Dosage and administration Shake well to mix before use and keep mixed during use. USE ALL PRODUCT WITHIN 42 DAYS OF OPENING. Vaccination program: It is recommended that cattle are vaccinated with a single 2 mL injection subcutaneously on the side of the neck. Vaccination should be undertaken in advance of situations with a high potential of environmental challenge with Mannheimia haemolytica causing BRD to occur. These situations may involve the assembly, mixing or movement of cattle - for example, dairy calves, being reared in groups, dairy cattle calving and entering the milking herd, cattle moving between herds or regions and cattle destined for feedlots. Significant immunological response achieved within 7 days with peak immunological response 14 days after a single dose vaccination and remains high for 180 days. CAUTION – AVOID CARCASS DAMAGE 1. Sterilise all metal injection apparatus by boiling for at least 20 minutes before use. Plastic injection apparatus should be flushed with cooled boiled water prior to use. Avoid use of strong disinfectants on apparatus. Cool before use. 2. Maintain cleanliness at all times. 3. Keep needles sharp at all times. Replace frequently. 4. As far as possible avoid injection of animals during wet weather or under dusty conditions. 5. This product should be injected only under the skin. Equipment: The vaccine bottle is designed so that it can be used with an automatic vaccination gun. To connect bottle to automatic vaccinator, attach the plain tube end of the draw-off assembly to the automatic vaccinator and the other end to the bottle. Suspend the bottle from the shoulder by means of the plastic cradle and the carrying strap. Eject air from the vaccinator and tubing until vaccine flows through the needle. A partially used pack can be stored and used for up to 42 days after first opening if the following steps are taken: 1. Remove the delivery tube from the vaccine pack. 2. Use or dispose of any residual vaccine from the delivery tube and vaccinator. 3. Disinfect the stopper with a suitable antiseptic. 4. Place the vaccine bottle in the original box and store upright in the refrigerator. DO NOT FREEZE. To reduce risk of contamination and leaking caused by multiple broaching of the stopper, it is recommended that the bottle should not be broached more than twice.

General Directions:	Onset of immunity: A significant immunological response is observed against Mannheimia haemolytica from 7 days after vaccination with one dose of Bovilis MH SS RTU. Peak immunological response occurs at 14 days, remaining high for 180 days (25 weeks). Bovine Respiratory Disease (BRD) is a complex disorder of cattle causing mild to severe respiratory disease and even death. It is caused by a combination of infectious agents and stress factors (marking, weaning, transport, saleyards, mixing, weather extremes, dust, handling, calving and change of diet) acting on susceptible cattle in paddock, feedlot and dairy systems. Mannheimia haemolytica is known to contribute to the development of BRD. Vaccination with Bovilis MH SS RTU has proven useful in the overall management of BRD. Calves are often exposed to the Mannheimia haemolytica (MH) bacterium that cause severe BRD early in life. Calves fed colostrum from cows vaccinated in late gestation will

	acquire passive immunity against bovine respiratory disease (BRD) caused by Mannheimia haemolytica. Bovilis MH SINGLE SHOT RTU can be administered as a two-dose vaccination program for cows to protect young calves via passive immunity. Cows should be vaccinated twice in the third trimester of pregnancy with an interval of 28 days between doses. The second dose should be administered at least 3 weeks prior to calving.

Withholding Periods:	Zero (0) days.

Trade Advice:	EXPORT SLAUGHTER INTERVAL (ESI): Zero (0) days.

Safety Directions:	

First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 131126.

First Aid Warnings:	

Additional User Safety:	This product contains a mineral oil and is an irritant. In the event of accidental self-administration, it can cause significant pain and swelling at the injection site, perhaps also involving the draining lymph nodes. Medical or surgical intervention may be required, especially if the site of injection involves a finger joint or tendon sheath. Contact a doctor as soon as possible, even if only a very small amount is injected, and take this package leaflet/ carton with you. Allow the wound to bleed freely and do not squeeze or interfere with the injection site to avoid spread of the vaccine. Advice to the medical practitioner This product contains mineral oil. Even if small amounts of this product have been accidentally self-administered, it can cause intense swelling and a persistent granulomatous inflammatory reaction. If injected into a finger joint or tendon sheath, the product may track along the tendon. The swelling and inflammation may compromise blood supply and result in necrosis that, in rare cases, may lead to the loss of a digit. Following appropriate immediate local cleansing, corticosteroids may be considered to decrease the severity of any local reaction. Ascertain the patient's tetanus immunisation status, and provide booster or primary series, as appropriate. In some cases of accidental self-injection, PROMPT surgical attention may be required. The wound should be incised and irrigated to remove the vaccine, especially where there is involvement of finger pulp or tendon. Complete curettage or total excision of the lesion may be required for chronic granulomatous reactions. Meticulous technique is required to stop inadvertent spread of the product. Additional information is listed in the safety data sheet.

Environmental Statements:	

Disposal:	Dispose of empty container by wrapping with paper and putting in garbage.

Storage:	Store between 2°C and 8°C (refrigerate, do not freeze). Protect from light. Keep out of reach of children.