

## SCOURGUARD 4(K) LABEL TEXT

**RESTRICTED VETERINARY MEDICINE  
KEEP OUT OF REACH OF CHILDREN  
FOR ANIMAL TREATMENT ONLY**

### **ScourGuard® 4(K)**

*Bovine Rotavirus – Coronavirus Killed Virus  
and Escherichia coli Bacterin*

100 mL (50 doses)

#### **READ ENTIRE LABEL BEFORE USE**

#### **PRODUCT DESCRIPTION**

ScourGuard 4(K) is for vaccination of healthy, pregnant cows and heifers as an aid in preventing disease in calves caused by bovine Group A rotavirus, bovine coronavirus, and enterotoxigenic strains of *Escherichia coli* having the K99 pili adherence factor. Vaccination of pregnant cows and heifers with ScourGuard 4(K) has also been shown to reduce bovine rotavirus shedding in calves.

ScourGuard 4(K) contains a liquid preparation of inactivated bovine rotavirus (serotypes G6 and G10) and coronavirus propagated on established cell lines, and a K99 *E. coli* bacterin. The vaccine is adjuvanted to enhance the immune response.

#### **EFFICACY**

ScourGuard 4(K) has been demonstrated to be effective as an aid in preventing disease caused by bovine Group A rotavirus, bovine coronavirus, and *E. coli* in calves of vaccinated dams.

Efficacy of the bovine rotavirus (BRV) and bovine coronavirus (BCV) fractions of ScourGuard 4(K) was demonstrated in a series of challenge studies conducted by Pfizer Animal Health. Healthy neonatal calves were removed from their dams prior to nursing, and were fed colostrum collected from heifers previously vaccinated with either ScourGuard 4(K) or a placebo. When challenged with BRV or BCV, calves fed colostrum from heifers vaccinated with ScourGuard 4(K) showed significant reductions in mortality and faecal rotaviral and coronaviral shedding when compared with calves consuming colostrum from control heifers. In addition, these calves had considerably less diarrhoea and their appetite, attitude and dehydration scores were significantly better than the control calves.

Additional studies, designed similarly to the previous studies, demonstrated the efficacy of the *E. coli* K99 fraction of ScourGuard 4(K). Following challenge, neonatal calves that were fed colostrum from heifers previously vaccinated with the *E. coli* K99 fraction of ScourGuard 4(K) showed significant reductions in mortality when compared with calves consuming colostrum from control heifers. Additionally, these calves had considerably less diarrhoea and their attitude, appetite and dehydration scores were significantly better than the control calves.

#### **SAFETY**

The safety of ScourGuard 4(K) in pregnant cows and heifers was demonstrated in 3 field safety studies conducted in 3 different geographic locations. No significant adverse events were observed in vaccinates following administration of ScourGuard 4(K).

## **DOSAGE AND ADMINISTRATION**

### **Directions for Use:**

#### *1. General Directions:*

Vaccination of healthy, pregnant cows and heifers is recommended. Shake well. Aseptically administer 2 mL intramuscularly only. This product should be administered in the muscular region of the neck.

#### *2. Primary Vaccination:*

Administer 2 intramuscular doses at least 3 weeks apart to pregnant cows or heifers, with the second dose given 2-12 weeks before calving.

#### *3. Revaccination:*

Revaccination with a single dose 2-12 weeks before each subsequent calving is recommended. ScourGuard 4(K) can also be given as an annual booster vaccination to animals vaccinated with Rotavec® Corona (A8132) in the previous year.

Since calf protection is dependent on the presence of passively acquired antibodies within the gastrointestinal system, calves must receive adequate colostrum from their dams. Newborn calves should be fed at least two litres of colostrum from the first milking, ideally within six hours of birth. Calves should continue to receive colostrum and/or milk from vaccinated cows for the duration of the critical neonatal period.

Milk collected from the first six to eight milkings of vaccinated cows should be pooled and reserved. According to body size, the calves should then be fed from this pool for at least the first two weeks of life, at a rate of 2½ to 4 litres per day.

Adoption of a whole herd cow vaccination policy will ensure optimum results. This will ensure that the level of calf infection and consequent virus shedding is minimised and, therefore, the overall level of disease challenge within the herd will be kept to a minimum.

## **WITHHOLDING PERIODS**

Nil

## **PRECAUTIONS**

1. Store at 2-8°C (Refrigerate). Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
2. Use entire contents when first opened.
3. Aseptic technique should be used to administer this vaccine.
4. Transient temperature increases may occur following vaccination.
5. As with many vaccines, anaphylaxis may occur after use. Initial antidote of adrenaline is recommended and should be followed with appropriate supportive therapy.
6. This product has been shown to be efficacious in healthy animals. A protective immune response may not be elicited if animals are incubating an infectious disease, are malnourished or parasitised, are stressed due to shipment or environmental conditions, are otherwise immuno-compromised, or the vaccine is not administered in accordance with label directions.

## **HANDLING PRECAUTIONS**

This material may cause a mild allergic reaction in sensitive individuals on skin contact. Avoid skin contact.

## **FIRST AID**

If swallowed, do NOT induce vomiting. If poisoning occurs, contact a doctor or Poisons Information Centre. Phone New Zealand 0800 POISON (0800 764 766). If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. If splashed in eyes, wash out immediately with water.

## **FURTHER INFORMATION**

Calf scours is a complex disease with a variety of causes. During the first few weeks of a calf's life, rotavirus, coronavirus and *E. coli* are three of the principal causative agents responsible for the development of scours. ScourGuard 4(K) will aid in protecting calves against disease progression due to these agents. As no vaccine currently offers absolute passive protection against these three infectious agents, infection may occur in calves from vaccinated dams, however, ScourGuard 4(K) will aid in containing the infection while the calf's immune system mounts its own active response.

In any given population, there may be a small number of animals in which vaccination is at least partially unsuccessful. Use of the vaccine in accordance with label directions together with a favourable response from the animal, are important factors in ensuring successful vaccination. This response may be influenced by factors including age, nutritional status, concurrent drug therapy or infection, and genetic disposition.

## **STORAGE**

Store between 2° - 8°C. Refrigerate. Do NOT freeze.

Once opened, use within 12 hours.

## **DISPOSAL**

Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill or other approved facility. Used needles should immediately be placed in a designated and appropriately labelled "sharps" container.

## **MODE OF ISSUE**

ScourGuard 4(K) is issued in vials of 20mL (10 doses) and 100mL (50 doses).

Registered pursuant to the ACVM Act 1997, No. A10057

See [www.nzfsa.govt.nz/acvm/](http://www.nzfsa.govt.nz/acvm/) for registration conditions.

Approved pursuant to the HSNO Act 1996, Approval Code HSR000015.

See [www.ermanz.govt.nz](http://www.ermanz.govt.nz) for approval controls.

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