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| **Registrant:** | Zoetis New Zealand Limited, 8 Mahuhu Crescent, Auckland | | |
| **Trade Name:** | SCOURGUARD® 4(K) | **ACVM No.:** | A10057 |
| **Preparation Date:** | 9 September 2014 | **Page:** | 1 of 8 |

## EXTENDED CONTENT LABEL
## Front Panel

**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

20mL (10 doses) [100 mL (50 doses)]

[Zoetis logo]

## EXTENDED CONTENT LABEL
## Side Panel

For the vaccination of healthy, pregnant cows and heifers as an aid in preventing diarrhoea in their calves caused by bovine rotavirus (serotypes G6 and G10), bovine coronavirus, and *E. coli* having the K99 pili adherence factor.

**READ ENTIRE LABEL BEFORE USE**

**Directions for Use:** Shake well. Aseptically administer 2 mL by intramuscular (IM) or subcutaneous (SC) injection into the anterior (front) half of the neck. Previously unvaccinated heifers or cows should receive two IM doses at least 3 weeks apart, with the second dose given 2-12 weeks prior to calving. Annual revaccination with a single dose 2-12 weeks prior to each subsequent calving is recommended. See enclosed leaflet for complete directions and precautions.

**Precautions:** Store at 2°-8°C. Do not freeze. Once opened, use within 63 days.

**Withholding Periods:** Nil

**RVM: ACVM No. A10057**

Zoetis New Zealand Limited
8 Mahuhu Crescent, Auckland
Technical Services 0800 650 277

Date First Opened: _____
SER:
EXP:

[label identifier]

MINISTRY FOR PRIMARY INDUSTRIES NEW ZEALAND

Maree Zinzley
Manager Approvals Operations
Regulation and Assurance

08 JUL 2015

**EXTENDED CONTENT LABEL**
**Inner pages**

# ScourGuard® 4(K)

[Cow & calf graphic]

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

## 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 Zoetis. 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 either BRV or BCV, calves fed colostrum from heifers vaccinated with ScourGuard 4(K) showed significant reductions in mortality and their appetite, attitude and dehydration scores were significantly better when compared with calves consuming colostrum from control heifers. In addition, these calves had considerably less diarrhoea than the control calves. Vaccination also significantly reduced faecal rotaviral shedding post BRV challenge compared to 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).

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## DOSAGE AND ADMINISTRATION

**Directions for Use:**

1. *General Directions:*
   Vaccination of healthy, pregnant cows and heifers is recommended. Shake well. Aseptically administer 2 mL by intramuscular or subcutaneous injection. This product should be administered in the anterior half of the neck.

2. *Primary Vaccination:*
   Administer 2 doses by intramuscular or subcutaneous injection 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.

SIDE EFFECTS:
Transient injection site swelling can be expected after subcutaneous vaccination, with resolution within 3 to 4 weeks.

## WITHHOLDING PERIODS

Nil

## PRECAUTIONS

1. Store at 2-8°C (Refrigerate). Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
2. Aseptic technique should be used to administer this vaccine.
3. Transient temperature increases may occur following vaccination.
4. As with many vaccines, anaphylaxis may occur after use. Initial antidote of adrenaline is recommended and should be followed with appropriate supportive therapy.
5. 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.

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**Resealing**
A partially used pack can be stored and used for up to 63 days after first opening if the following steps are taken
1. Remove the delivery tube from the vaccine pack
2. Empty the delivery tube and vaccinator by depressing the plunger several times
3. Disinfect the stopper with a suitable antiseptic, (e.g. methylated spirits)
4. Place the vaccine pack in the original outer packaging and store upright in the refrigerator. Do not freeze

Before re-use, the delivery tube and cap should be sterilized by boiling for at least ten minutes
NOTE: The plastic delivery tube may become opaque
Frequent attachment of the connecting tube may cause the stopper to leak
Therefore, the tube should not be attached more than twice

**IMPORTANT USER SAFETY INFORMATION**
**Avoid self inoculation.** Accidental self-injection may cause an inflammatory or allergic response and medical advice should be sought in these cases. Deep injections, particularly if they are near a joint or associated with local bruising may require medical management.

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

**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).

**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 63 days.

**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).

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**Restricted Veterinary Medicine**
Registered pursuant to the ACVM Act 1997, No. A10057
See www.foodsafety.govt.nz for registration conditions.
Approved pursuant to the HSNO Act 1996, Approval Code HSR000015.
See www.epa.govt.nz for approval controls.

[Zoetis logo] Made in the USA
**Zoetis** New Zealand Limited
8 Mahuhu Crescent, Auckland
Technical Services 0800 650 277
www.zoetis.co.nz



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**CARTON LABEL (Note: Carton is optional)**
**Main Panel**

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

## ScourGuard® 4(K)

[Cow & calf picture]

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

10 x 10 dose (20 mL) vials [10 x 50 dose (100 mL) vials]

[Zoetis logo]

**CARTON LABEL**
**Top Panel**

## ScourGuard® 4(K)

[Zoetis logo]

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

10 x 10 dose (20 mL) vials [10 x 50 dose (100 mL) vials

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**CARTON LABEL**
**Rear Panel**

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 (serotypes G6 and G10), 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.

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**Withholding Periods:** Nil

**Storage:** Store between 2° - 8°C. Refrigerate. Do NOT freeze. Once opened, use within 63 days.

Registered pursuant to the ACVM Act 1997, No. A10057
See www.foodsafety.govt.nz for registration conditions.
Approved pursuant to the HSNO Act 1996, Approval Code HSR000015
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[Zoetis logo] Made in the USA
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[EAN Barcode]

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**CARTON LABEL**
**Left Panel**

**Precautions:**
1. Store at 2-8°C (Refrigerate). Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
2. Aseptic technique should be used to administer this vaccine.
3. Transient temperature increases may occur following vaccination.
4. As with many vaccines, anaphylaxis may occur after use. Initial antidote of adrenaline is recommended and should be followed with appropriate supportive therapy.
5. 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.

SER:

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**CARTON LABEL**
**Right Panel**

**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.

**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.

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