SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rotavec Corona Emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 2 ml dose:

Active Substances	
Bovine rotavirus, strain UK-Compton, serotype G6 P5 (inactivated)	¼ dose of vaccine stimulates a virus neutralising antibody titre: ≥ 7.7 log_2/ml (guinea pigs).
Bovine coronavirus, strain Mebus (inactivated)	1/20 dose of vaccine stimulates an ELISA antibody titre: ≥ 3.41 log_{10}/ml (guinea pigs).
E. coli F5 (K99) adhesin	1/20 dose of vaccine stimulates an ELISA antibody (OD492): > 0.64 (guinea pigs).
Adjuvant	
Light Mineral Oil / emulsifier	1.40 ml
Aluminium hydroxide	2.45 - 3.32 mg
Excipients	
Thiomersal	0.032 - 0.069 mg
Formaldehyde	≤0.34 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (pregnant cows and heifers)

4.2 Indications for use, specifying the target species

For the active immunisation of pregnant cows and heifers to raise antibodies against *E. coli* adhesin F5 (K99) antigen, rotavirus and coronavirus. While calves are fed colostrum from vaccinated cows during the first two to four weeks of life, these antibodies have been demonstrated to:
- reduce the severity of diarrhoea caused by *E. coli* F5 (K99)
- reduce the incidence of scours caused by rotavirus
- reduce the shedding of virus by calves infected with rotavirus or coronavirus.

Onset of Immunity : Passive protection against all active substances will commence from the start of colostrum feeding
Duration of Immunity : In calves artificially fed with pooled colostrum, protection will continue until colostrum feeding ceases. In naturally suckled calves, protection against rotavirus will persist for at least 7 days and against coronavirus for at least 14 days.

4.3 Contraindications

None

4.4 Special warnings

None

4.5 Special precautions for use

Particularly strict precautions should be taken against contamination of the vaccine

i) Special precautions for use in animals

Do not vaccinate unhealthy animals.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Occasionally a soft swelling raised up to 1 cm may be observed at the site of injection, which will resorb within 14 to 21 days.

Occasional hypersensitivity reactions may occur. In such cases appropriate treatment such as adrenaline should be administered without delay.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Before use shake well. Syringes and needles should be sterilised before use and the injection should be made through an area of clean, dry skin taking precautions against contamination.

Administration:
One dose of 2 ml by intramuscular injection.
The recommended site is the side of the neck.
A single injection should be given during each pregnancy between 12 and 3 weeks before calving is expected.

Colostrum feeding:
Protection of calves depends on the physical presence of colostrum antibodies (from vaccinated cows) within the gut for the duration of the first 2 - 3 weeks of life until calves develop their own immunity. Thus it is essential to ensure adequate colostrum feeding for the whole of this period to maximise the efficacy of vaccination. All calves must receive adequate colostrum from their dams within 6 hours of birth. Suckled calves will continue to receive adequate colostrum naturally by feeding from vaccinated cows.
In the dairy herd colostrum/milk from the first 6 - 8 milkings of vaccinated cows should be pooled. The colostrum may be stored below 20 °C but should be used as soon as possible as immunoglobulin levels may fall by up to 50% after storage for 28 days. Where possible, storage at 4 °C is recommended. The calves should be fed on this pool at the rate of 2½ to 3½ litres per day (according to body size) for the first two weeks of life.

Optimal results will be obtained if a whole herd cow vaccination policy is adopted. This will ensure that in calves the level of infection and consequent virus excretion is kept to a minimum and consequently the overall level of disease challenge on the farm is minimised.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

On administration of an intramuscular injection of not more than double the recommended dose, a reaction no more severe than after administration of a single dose may occur.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral and inactivated bacterial vaccines for cattle
ATCvet code: QI02AL01

The vaccine contains a rotavirus from group A (serotype G6P5), a coronavirus and Escherichia coli F5(K99) pilus antigen. These components are inactivated and adjuvanted with mineral oil and aluminium hydroxide.
The vaccine is intended to stimulate active immunity in order to provide passive immunity to the progeny against active substances.
Passive protection against all active substances will commence from the start of colostrum feeding. In calves artificially fed with pooled colostrum, protection will continue until colostrum feeding ceases. In naturally suckled calves, protection against rotavirus will persist for at least 7 days and against coronavirus for at least 14 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Formaldehyde
Sodium thiosulphate
Sodium chloride

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 8 hours

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C)
Protect from light
Do not freeze

6.5 Nature and composition of immediate packaging

White neutral glass vial, Type I (Eu. Ph.). 2 ml (1 dose), 10 ml (5 doses) and 40 ml (20 doses).
Nitrile grey rubber closure with Omniflex fluorinated polymer coating and an aluminium seal.

10 ml and 40 ml sizes packed in individual cardboard outer cartons, 2 ml sizes packed as 10 x 2 ml in a cardboard outer carton.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3921 ZB Breukelen
The Netherlands

8. MARKETING AUTHORISATION NUMBER

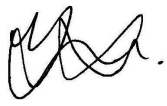
Vm 43877/4002

9. DATE OF FIRST AUTHORISATION

07 December 2015

10. DATE OF REVISION OF THE TEXT

December 2015



Approved: 07 December 2015