Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Rotavec Corona emulsion for injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances

Bovine rotavirus inactivated, strain UK-Compton, serotype G6 P5	≥ 874 U[1]
Bovine coronavirus inactivated, strain Mebus	≥ 3.41 $\log_{10}$/ml ELISA antibody titre[2]
E. coli F5 (K99) adhesin	≥ 0.64 ELISA antibody OD value[2]

[1] Units as determined in the *in vitro* potency test (ELISA)
[2] Obtained in *in vivo* potency test

Adjuvants

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 the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection.
Off-white emulsion.

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 for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Particularly strict precautions should be taken against contamination of the vaccine.

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
To the user:
This veterinary medicinal 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 veterinary medicinal 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)

A soft swelling raised up to 1 cm was observed very commonly at the site of injection during safety and clinical studies. These swellings usually resorb within 14 to 21 days.
Hypersensitivity reactions were observed in spontaneous pharmacovigilance reports in very rare cases. In such cases, appropriate treatment such as adrenaline should be administered without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

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

Intramuscular use.

Shake well before use. 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.
Strict precautions should be taken against contamination of the vaccine. The use of a multi-dose syringe is recommended to avoid excessive broaching of the stopper. Once a vial is broached for the first time it may be used once more during the next 28 days and then discarded immediately after that use.

Administration:
Administer a single dose of 2 ml per animal. The recommended site of injection 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(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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

The vaccine contains a rotavirus from group A (serotype G6 P5), 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

Light mineral oil (Emulsifier)
Aluminium hydroxide
Thiomersal
Formaldehyde
Sodium thiosulphate
Sodium chloride

6.2 Major 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: 28 days.
The content of the vial should not be used beyond 28 days after first broaching.

6.4 Special precautions for storage

Store and transport refrigerated (2°C - 8°C).
Do not freeze.
Protect from light.
After broaching and first use, store upright and refrigerated (2 - 8 °C) until the next vaccination event.

6.5 Nature and composition of immediate packaging

Type I glass vial with 2 ml, 10 ml, 40 ml or 100 ml, closed with a halobutyl rubber stopper and an aluminium cap.
PET (polyethylene terephthalate) vial with 10 ml, 40 ml, or 100 ml, closed with a halobutyl or nitrile chlorobutyl rubber stopper and an aluminium cap.
Pack sizes:
Cardboard box with 10 x 2 ml (10 x 1 dose).
Cardboard box with 1 x 10 ml (5 doses).
Cardboard box with 1 x 40 ml (20 doses).
Cardboard box with 1 x 100 ml (50 doses).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/216/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 August 2000
Date of last renewal: 07 July 2010

10 DATE OF REVISION OF THE TEXT

October 2020