1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Rotavec Corona emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:

Bovine rotavirus, serotype G6 P5, strain UK-Compton, inactivated	≥ 874 U[1]
Bovine coronavirus, strain Mebus, inactivated	≥ 340 U[2]
E. coli, serotype O101:K99:F41, strain CN7985, fimbrial adhesins F5 and F41, inactivated	≥ 560 U[3]

[1] Units as determined in the BRV potency ELISA
[2] Units as determined in the BCV potency ELISA
[3] Units as determined in the *E. coli* F5 (K99) potency ELISA

Adjuvants:

Light mineral oil / emulsifier	1.40 ml
Aluminium hydroxide	2.45 - 3.32 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.032 - 0.069 mg
Formaldehyde	
Sodium chloride	

Off-white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (pregnant cows and heifers).

3.2 Indications for use for each target species

For the active immunisation of pregnant cows and heifers to raise antibodies against *E. coli* adhesins F5 (K99) and F41, 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) and F41
- 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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Administration in the ischiorectal fossa resulted in local painful chronic granulomatous reactions up to 12 cm in diameter and in abscess formation (up to 1 cm in diameter at post mortem 19 weeks after the first vaccination).

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 veterinary medicinal 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 veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle (pregnant cows and heifers):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], injection site pain[2], injection site warmth[2], injection site granuloma[3] Muscle inflammation[4] Injection site abscess[5]
Common 1 to 10 animals / 100 animals treated:	Elevated temperature[6]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[7]

[1] Intramuscular administration: Soft swelling raised up to 1 cm and a diameter of on average 6.5 cm (maximum of 25 cm). Swellings usually resorb within 14 to 21 days but may persist for 125 days.
Subcutaneous administration in the neck: Swelling raised up to 1 cm and ranged from 2x2 to 15x15 cm (LxW). Swellings usually resorb over time but may persist for 125 days.

[2] Injection site pain and injection site warmth occur reportedly commonly, when administered intramuscularly.
[3] After subcutaneous administration in the ischiorectal fossa.
[4] Subcutaneous administration in the ischiorectal fossa resulted in granulomatous haemorrhagic inflammatory reaction in dermal and subdermal tissues with inflammation extending into the underlying muscular tissue.
[5] Less than 1 cm in diameter after subcutaneous administration in the ischiorectal fossa.
[6] Intramuscular administration: Average increase of 0.4 °C, with a maximum of more than 2.0 °C, returning to normal the day after vaccination.
Subcutaneous administration in the ischiorectal fossa: Average increase of 0.4 °C, with a maximum of more than 2.0 °C, returning to normal in one to two days after vaccination.
[7] In such cases, appropriate treatment such as adrenaline should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Bovilis Cryptium. The vaccines should be given at different sites.
The product literature of Bovilis Cryptium should be consulted before administration. After non-mixed associated use injection site swellings raised up to 1 cm and a diameter of on average 7.6 cm (maximum of 30 cm) can be observed. Swellings usually resorb within 14 to 21 days but may persist for 18 weeks.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.

3.9 Administration routes and dosage

Intramuscular or subcutaneous use.
Preferably administer the vaccine in the side of the neck.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No reactions other than those described in section 3.6 occurred following the administration of a two-fold overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI02AL01.

The vaccine contains a rotavirus from group A (serotype G6 P5), a coronavirus and *Escherichia coli* F5 (K99)-F41 pilus antigens. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 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.

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/216/001

8. DATE OF FIRST AUTHORISATION

24/09/2010

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

13/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).