SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DiarrVac RCE
Emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of the vaccine (3 ml) contains:

Active substance:

Bovine rotavirus strain TM-91, serotype G6P1 (inactivated)	≥ 6.0 $\log_2$ (VNT)*
Bovine coronavirus strain C-197 (inactivated)	≥ 5.0 $\log_2$ (HIT)**
Escherichia coli strain EC/17 (inactivated) expressing F5 (K99) adhesin	≥ 44.8% of inhibition (ELISA)***

*VNT – virus neutralisation test (rabbit serology induced by 2/3 dose of vaccine)
**HIT – haemagglutination inhibition test (rabbit serology induced by 2/3 dose of vaccine)
***ELISA – Enzyme-linked immunosorbent assay (rabbit serology induced by 2/3 dose of vaccine)

Adjuvant:

Montanide ISA 206 VG	1.6 ml

Excipients:

Formaldehyde	max. 1.5 mg
Thiomersal	max. 0.36 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White liquid emulsion which may form a sediment during storage.

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* adhesion F5 (K 99) antigen, rotavirus and coronavirus. When calves are fed colostrum from vaccinated cows during the first week of life, these antibodies have been demonstrated to reduce the severity of diarrhoea caused by bovine rotavirus, bovine coronavirus and enteropathogenic *E. coli* F5 (K99) and to reduce the shedding of virus by calves infected with bovine rotavirus or bovine coronavirus.

Onset of immunity: Passive immunity commences with colostrum feeding and is dependent on calves receiving sufficient colostrum after birth.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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 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 ischemic 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 slight swelling of 5-7 cm in diameter at the site of injection is common and may in some cases be accompanied initially by increased local temperature. Typically, such swelling resolves within 15 days. Slight, transient increases in temperature (up to 0.8 °C) may be observed within 24 hours of vaccination, resolving within 4 days after vaccination.

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

This veterinary medicinal product is intended for use in the last trimester of 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

For intramuscular use.
Common aseptic procedures should be used during vaccination. Only sterile syringes and needles should be used.
Allow the vaccine to reach room temperature before use. Shake well before and occasionally during use to ensure that the sediment is dissolved prior to administration.

For the 90 ml and 450 ml pack sizes, it is recommended to use automated dosing equipment to protect the stopper against damage from multiple piercing.

One dose: 3 ml
One dose in the course of each pregnancy, given in the 12–3 week period before calving is expected.

Feeding of colostrum

The protection of calves depends on adequate ingestion of colostrum from vaccinated cows. Measures should be taken to ensure that calves receive sufficient amounts of colostrum within the first few days of life. If calves do not get enough antibodies through the colostrum soon after they are born, they will have failure of passive transfer of antibodies. It is important that all calves receive as much colostrum as possible from the first milking within the first six hours after calving. It is recommended that at least 3 litres of colostrum are fed within the first 24 hours and this amount is equivalent to approximately 10% of the weight of a calf.

To achieve optimum results and to reduce infection pressure on the farm, a whole herd cow vaccination policy should be adopted.

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

Following the administration of an overdose, no adverse reactions other than those mentioned in section 4.6 occur.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI02AL01.

Pharmacotherapeutic group: immunologicals for Bovidae, inactivated viral and inactivated bacterial vaccines for cattle.
The vaccine is designed for stimulation of the active immunity of pregnant cows against the antigenic components included in the vaccine. The antibodies are transferred to the calf via colostrum.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA 206 VG
Formaldehyde
Thiomersal
Eagle's minimum essential medium (MEM)
Disodium phosphate dodecahydrate
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Water for injections

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: 3 years.
Shelf-life after first opening the immediate packaging: 10 days.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Glass vials, type I (15 ml, 90 ml) closed with chlorobutyl rubber stoppers or glass bottle, type I (450 ml) closed with bromobutyl rubber stoppers sealed with aluminium caps.

Plastic bottles (450 ml) closed with chlorobutyl rubber stoppers and sealed with aluminium caps without outer package.

Package sizes:
Cardboard box with 1 vial of 15 ml (5 doses)
Cardboard box with 1 vial of 90 ml (30 doses)
Cardboard box with 1glass bottle of 450 ml (150 doses)
Plastic bottle with 450 ml (150 doses)

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Forte Healthcare Ltd
Cougar Lane
Naul
Co Dublin
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 27819/3000

9. DATE OF FIRST AUTHORISATION

11 March 2022

10. DATE OF REVISION OF THE TEXT

September 2023

Approved 23 February 2024