1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVIGEN SCOUR emulsion for injection for cattle (AT, BE, CY, DE, EE, EL, FR, HR, IE, IT, LV, LT, LU, MT, NL, PT, RO, SI, UK)
BOVIGEN RCE Vet emulsion for injection for cattle (DK, FI, NO, SE)
BOVISAN DIAR emulsion for injection for cattle (ES)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 ml dose contains:

Active substances:
Bovine rotavirus A, type G6P1, strain TM-91, inactivated ≥ 6.0 log2 (VNT)*
Bovine coronavirus, strain C-197,inactivated ≥ 5.0 log2 (HIT)**
Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, inactivated
≥ 44.8 % of inhibition (ELISA F5)***

*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)

Adjuvants:

Montanide ISA 206 VG 1.6 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde	max. 1.5 mg
Thiomersal	max. 0.36 mg
Eagle's Minimum Essential Medium (MEM)	
Disodium phosphate dodecahydrate	
Sodium chloride	
Potassium chloride	
Potassium dihydrogen phosphate	
Water for injections	

White liquid emulsion which may form a sediment during storage.

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* 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.

Duration of immunity: has not been established.

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:

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 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):

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1], elevated temperature[2]

[1] 5-7 cm in diameter which typically resolves within 15 days.
[2] Increases up to 0.8 °C may be observed within 24 hours of vaccination, resolving within 4 days.

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 the last trimester of pregnancy.

3.8 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.

3.9 Administration routes and dosage

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.

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

Following the administration of an overdose, no adverse reactions other than those mentioned in section 3.6 occur.

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

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.
E. coli vaccine strain has been qualitatively confirmed to produce F5 and F41 adhesins. The presence of F41 adhesin has not been quantified.

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

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Protect from light. Do not freeze.
After broaching and first use, store upright and refrigerated (2 °C – 8 °C) until the next use.

5.4 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 1 glass bottle of 450 ml (150 doses)
Plastic bottle with 450 ml (150 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

FORTE Healthcare Ltd

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

MM/YYYY

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box for glass vial (15 ml, 90 ml) and bottle (450 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVIGEN SCOUR emulsion for injection(AT, BE, CY, DE, EE, EL, FR, HR, IE, IT, LV, LT, LU, MT, NL, PT, RO, SI, UK)
BOVIGEN RCE Vet emulsion for injection (DK, FI, NO, SE)
BOVISAN DIAR emulsion for injection (ES)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 ml dose contains:
Active substances:
Bovine rotavirus A, type G6P1, strain TM-91, inactivated ≥ 6.0 log2 (VNT)*
Bovine coronavirus, strain C-197,inactivated ≥ 5.0 log2 (HIT)**
Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, inactivated
≥ 44.8 % of inhibition (ELISA F5)***

*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)

3. PACKAGE SIZE

15 ml (5 doses)
90 ml (30 doses)
450 ml (150 doses)

4. TARGET SPECIES

Cattle (pregnant cows and heifers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Protect from light. Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

FORTE Healthcare Ltd

Local representative/Distributor: *to be completed nationally*

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Label for plastic bottle (450 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVIGEN SCOUR emulsion for injection(AT, BE, CY, DE, EE, EL, FR, HR, IE, IT, LV, LT, LU, MT, NL, PT, RO, SI, UK)
BOVIGEN RCE Vet emulsion for injection (DK, FI, NO, SE)
BOVISAN DIAR emulsion for injection (ES)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 ml dose contains:
Active substances:
Bovine rotavirus A, type G6P1, strain TM-91, inactivated ≥ 6.0 log2 (VNT)*
Bovine coronavirus, strain C-197, inactivated ≥ 5.0 log2 (HIT)**
Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, inactivated
≥ 44.8 % of inhibition (ELISA F5)***

*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)

3. PACKAGE SIZE

450 ml (150 doses)

4. TARGET SPECIES

Cattle (pregnant cows and heifers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 days.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Protect from light. Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

FORTE Healthcare Ltd

Local representative/Distributor: *to be completed nationally*

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for glass vial (90 ml), and glass bottle (450 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVIGEN SCOUR emulsion for injection (AT, BE, CY, DE, EE, EL, FR, HR, IE, IT, LV, LT, LU, MT, NL, PT, RO, SI, UK)
BOVIGEN RCE Vet emulsion for injection (DK, FI, NO, SE)
BOVISAN DIAR emulsion for injection (ES)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 3 ml dose contains:
Active substances:
Bovine rotavirus A, type G6P1, strain TM-91, inactivated ≥ 6.0 log2 (VNT)
Bovine coronavirus, strain C-197, inactivated ≥ 5.0 log2 (HIT)
Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, inactivated
≥ 44.8 % of inhibition (ELISA F5)

3. TARGET SPECIES

Cattle (pregnant cows and heifers).

4. ROUTES OF ADMINISTRATION

Intramuscular use. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 days.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator. Protect from light. Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

FORTE Healthcare Ltd

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{Label for glass vial (15 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVIGEN SCOUR emulsion for injection for cattle (AT, BE, CY, DE, EE, EL, FR, HR, IE, IT, LV, LT, LU, MT, NL, PT, RO, SI, UK)
BOVIGEN RCE Vet emulsion for injection for cattle (DK, FI, NO, SE)
BOVISAN DIAR emulsion for injection for cattle (ES)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 3 ml dose contains:
Active substances:
Bovine rotavirus A, type G6P1, strain TM-91, inactivated ≥ 6.0 log2 (VNT)
Bovine coronavirus, strain C-197, inactivated ≥ 5.0 log2 (HIT)
Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, inactivated
≥ 44.8 % of inhibition (ELISA F5)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

BOVIGEN SCOUR emulsion for injection (AT, BE, CY, DE, EE, EL, FR, HR, IE, IT, LV, LT, LU, MT, NL, PT, RO, SI, UK)
BOVIGEN RCE Vet emulsion for injection (DK, FI, NO, SE)
BOVISAN DIAR emulsion for injection (ES)

2. Composition

Each 3 ml dose contains:

Active substances:
Bovine rotavirus A, type G6P1, strain TM-91, inactivated ≥ 6.0 log2 (VNT)*
Bovine coronavirus, strain C-197. inactivated ≥ 5.0 log2 (HIT)**
Escherichia coli, serotype O9:K35 (fimbrial adhesins F5 and F41), strain EC/17, inactivated
≥ 44.8 % of inhibition (ELISA F5)***

*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)

Adjuvants:
Montanide ISA 206 VG 1.6 ml

Excipients:
Formaldehyde max. 1.5 mg
Thiomersal max. 0.36 mg

White liquid emulsion which may form a sediment during storage.

3. Target species

Cattle (pregnant cows and heifers).

4. Indications for use

For the active immunisation of pregnant cows and heifers to raise antibodies against *E coli* adhesion F5 (K99) 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 colostrum after birth.

Duration of immunity: has not been established.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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 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.

Pregnancy:
Can be used during the last trimester of pregnancy.

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.

Overdose:
Following the administration of an overdose, no adverse reactions other than those mentioned in section "Adverse events" occur.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle (pregnant cows and heifers):

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1], elevated temperature[2]

[1] 5-7 cm in diameter which typically resolves within 15 days.
[2] Increases up to 0.8 °C may be observed within 24 hours of vaccination, resolving within 4 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Intramuscular use.
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.

9. Advice on correct administration

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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (2 ºC – 8 °C). Protect from light. Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 days.
After broaching and first use, store upright and refrigerated (2 °C – 8 °C) until the next use.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number – *to be completed nationally*
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 1 glass bottle of 450 ml (150 doses)
Plastic bottle with 450 ml (150 doses)

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}- *to be completed nationally*

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

16. Contact details

Marketing authorisation holder:
FORTE Healthcare Ltd
Cougar Lane
Naul
Co Dublin
Ireland

Manufacturer responsible for batch release:
PHARMAGAL BIO, s. r. o.
Murgašova 5
949 01 Nitra
Slovak Republic

Local representatives and contact details to report suspected adverse events: *to be completed nationally*

17. Other information

E. coli vaccine strain has been qualitatively confirmed to produce F5 and F41 adhesins. The presence of F41 adhesin has not been quantified.