ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Corona Coli, emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Inactivated bovine rotavirus, strain TM-91:	RP* ≥ 1
Inactivated bovine coronavirus, strain C-197:	RP* ≥ 1
Inactivated *E. coli* expressing F5 (K99) adhesin, strains 3014, 3015 and 3016:	RP* ≥ 1

*RP = Relative potency established in guinea pigs by a serological method (ELISA) in comparison with a standard vaccine with minimal content of antigen.

Adjuvant:

Montanide ISA VG70	ad 2 ml

Excipients:

Thiomersal	0.2 mg
Formaldehyde	max. 1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White to pinkish oily fluid containing a sediment that can be easily resuspended.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (pregnant heifers and cows).

4.2 Indications for use, specifying the target species

Active immunisation of pregnant heifers and cows for the purpose of passive immunisation of calves against gastro-enteric diseases caused by rotavirus, coronavirus and enteropathogenic *E. coli* strains.

Onset of immunity:
In calves fed from mothers and in calves fed with colostrum collected from the vaccinated cows the passive protection starts when feeding begins.

Duration of immunity:
In calves fed with colostrum collected from the vaccinated cows their passive protection against infection lasts until feeding with colostrum is interrupted.
The calves fed from mothers are protected against the infection by colostral and lactogenic immunity for the first 2 – 4 weeks of life.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
All breeding animals in the stock should be vaccinated. Adequate colostrum volume shall be administered to calves not later than 6 hours after their birth.

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 with the product 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)

Hypersensitivity reactions may occur rarely. In such a case it is necessary to start with appropriate treatment immediately.

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

The vaccine is intended for vaccination of pregnant breeding animals.

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

Vaccine administration:
Vaccine dose - 2 ml.
The vaccine is administered intramuscularly – preferably in the gluteal region.
Warm the vaccine to a temperature between 15°C – 25°C and shake the content of the vial before use.

Basic vaccination: pregnant heifers and naïve cows are vaccinated twice with an interval of 21 days, approximately , 7 – 5 weeks and 4 – 2 weeks before the first expected calving.
Revaccination: single vaccination, 4 - 2 weeks before each next calving.

Feeding with colostrum:
In order to ensure the effective protection of calves against infection, the gastrointestinal tract of calves shall be saturated with colostrum obtained from the vaccinated cows for the first 2 – 3 weeks of their life. A calf shall drink the adequate colostrum volume obtained from the vaccinated cows within 6 hours after its birth.
If a calf is not allowed to suckle with its mother, colostrum (and later milk) should be collected from the vaccinated cows during the first 6 – 8 milkings. The colostrum and milk obtained as above should be stored either frozen or (no longer than 14 days) at 2 °C - 8 °C. The daily dose of colostrum (and, later, milk) for a calf is 2.5 – 3.5 l daily for at least the first two weeks of life.
Optimum protection of calves against the infection can be reached using the method as mentioned above if all cows in the herd are vaccinated.

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

After administration of a double dose of the vaccine no other adverse reactions than those described in section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

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

Vaccination of pregnant heifers and cows induces formation of the specific colostral antibodies against both the viral and bacterial antigens contained in the vaccine (bovine rotavirus, bovine coronavirus and 3 serovars of the inactivated enteropathogenic *E. coli* strains expressing F5 (K99) adhesin).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA VG 70
Thiomersal
Formaldehyde
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dodecahydrate
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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: 10 hours.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

The vaccine is dispatched in:

1) hydrolytic class I glass vials:
   2 x 2 ml (2 x 1 dose), 10 x 2 ml (10 x 1 dose), 20 x 2 ml (20 x 1 dose)
   1 x 10 ml (1 x 5 doses), 5 x 10 ml (5 x 5 doses), 10 x 10 ml (10 x 5 doses)
2) hydrolytic class II glass vials:
   1 x 50 ml (1 x 25 doses), 12 x 50 ml (12 x 25 doses), 24 x 50 ml (24 x 25 doses)
   1 x 100 ml (1 x 50 doses), 12 x 100 ml (12 x 50 doses), 20 x 100 ml (20 x 50 doses)
3) HDPE bottles:
   1 x 10 ml (1 x 5 doses), 5 x 10 ml (5 x 5 doses), 10 x 10 ml (10 x 5 doses)
   1 x 50 ml (1 x 25 doses), 12 x 50 ml (12 x 25 doses), 24 x 50 ml (24 x 25 doses)
   1 x 100 ml (1 x 50 doses), 12 x 100 ml (12 x 50 doses), 20 x 100 ml (20 x 50 doses)

Vials and bottles are closed with a chlorobutyl pierceable stopper sealed with an aluminium cap. In case of the mass packages the vials are located in cardboard box fitted with a grid.

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
3621 ZB Breukelen
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box,
50 ml, 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Corona Coli, emulsion for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Active substances:

Inactivated bovine rotavirus, strain TM-91:	RP* ≥ 1
Inactivated bovine coronavirus, strain C-197:	RP* ≥ 1
Inactivated *E. coli* expressing F5 (K99) adhesin, strains 3014, 3015 and 3016:	RP* ≥ 1

*RP = Relative potency established in guinea pigs by a serological method (ELISA) in comparison with a standard vaccine with minimal content of antigen.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

10 ml (5 doses)
50 ml (25 doses)
100 ml (50 doses)
2 × 2 ml (2 x 1 dose)
10 × 2 ml (10 x 1 dose)
20 x 2 ml (20 x 1 dose)
5 x 10 ml (5 x 5 doses)
10 x 10 ml (10 x 5 doses)
12 x 50 ml (12 x 25 doses)
24 x 50 ml (24 x 50 doses)
12 x 100 ml (12 x 50 doses)
20 x 100 ml (20 x 50 doses)

5. TARGET SPECIES

Cattle (pregnant heifers and cows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}
Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

2 ml, 10 ml hydrolytic class I glass vial
10 ml HPDE vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Corona Coli, emulsion for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated bovine rotavirus, bovine coronavirus, *E.coli*

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose (2 ml)
5 doses (10 ml)

4. ROUTE(S) OF ADMINISTRATION

i.m.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
FIXR Rota Corona Coli, emulsion for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

Manufacturer responsible for batch release:
Bioveta, a. s.,
Komenského 212/12
683 23 Ivanovice na Hané
Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Corona Coli, emulsion for injection for cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 2 ml dose contains:

Active substances:

Inactivated bovine rotavirus, strain TM-91:	RP* ≥ 1
Inactivated bovine coronavirus, strain C-197:	RP* ≥ 1
Inactivated *E. coli* expressing F5 (K99) adhesin, strains 3014, 3015 and 3016:	RP* ≥ 1

*RP = Relative potency established in guinea pigs by a serological method (ELISA) in comparison with a standard vaccine with minimal content of antigen.

Adjuvant:

Montanide ISA VG70	ad 2 ml

Excipients:

Thiomersal	0.2 mg
Formaldehyde	max. 1 mg

4. INDICATION(S)

Active immunisation of pregnant heifers and cows for the purpose of passive immunisation of calves against gastro-enteric diseases caused by rotavirus, coronavirus and enteropathogenic *E. coli* strains.

Onset of immunity:
In calves fed from mothers and in calves fed with colostrum collected from the vaccinated cows the passive protection starts when feeding begins.

Duration of immunity:
In calves fed with colostrum collected from the vaccinated cows their passive protection against infection lasts until feeding with colostrum is interrupted.
The calves fed from mothers are protected against the infection by colostral and lactogenic immunity for the first 2 – 4 weeks of life.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Hypersensitivity reactions may occur rarely. In such a case it is necessary to start with appropriate treatment immediately.

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (pregnant heifers and cows).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Vaccine administration:
Vaccine dose - 2 ml.
The vaccine is administered intramuscularly – preferably in the gluteal region.
Basic vaccination: pregnant heifers and naïve cows are vaccinated twice with an interval of 21 days, approximately, 7 – 5 weeks and 4 – 2 weeks before the first expected calving.
Revaccination: single vaccination, 4-2 weeks before each next calving.

Feeding with colostrum:
In order to ensure the effective protection of calves against infection, the gastrointestinal tract of calves shall be saturated with colostrum obtained from the vaccinated cows for the first 2 – 3 weeks of their life. A calf shall drink the adequate colostrum volume obtained from the vaccinated cows within 6 hours after its birth.
If a calf is not allowed to suckle with its mother, colostrum (and later milk) should be collected from the vaccinated cows during the first 6 – 8 milkings. The colostrum and milk obtained as above should be stored either frozen or (no longer than 14 days) at 2 °C - 8 °C. The daily dose of colostrum (and, later, milk) for a calf is 2.5 – 3.5 l daily for at least the first two weeks of life.
Optimum protection of calves against the infection can be reached using the method as mentioned above if all cows in the herd are vaccinated.

9. ADVICE ON CORRECT ADMINISTRATION

Warm the vaccine to a temperature between 15°C – 25°C and shake the content of the vial before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C - 8°C).

Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.
All breeding animals in the stock should be vaccinated. Adequate colostrum volume shall be administered to calves not later than 6 hours after their birth.

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 with the product 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 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.

Pregnancy and lactation:
The vaccine is intended for the vaccination of the pregnant breeding animals.

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 (symptoms, emergency procedures, antidotes):
After administration of a double dose of the vaccine no other adverse reactions than those described in the section “Adverse reactions” have been observed.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION>

For animal treatment only.

To be supplied only on veterinary prescription.

The vaccine is dispatched in:

1) hydrolytic class I glass vials:
   2 x 2 ml (2 x 1 dose), 10 x 2 ml (10 x 1 dose), 20 x 2 ml (20 x 1 dose)
   1 x 10 ml (1 x 5 doses), 5 x 10 ml (5 x 5 doses), 10 x 10 ml (10 x 5 doses)
2) hydrolytic class II glass vials:
   1 x 50 ml (1 x 25 doses), 12 x 50 ml (12 x 25 doses), 24 x 50 ml (24 x 25 doses)
   1 x 100 ml (1 x 50 doses), 12 x 100 ml (12 x 50 doses), 20 x 100 ml (20 x 50 doses)
3) HDPE bottles:
   1 x 10 ml (1 x 5 doses), 5 x 10 ml (5 x 5 doses), 10 x 10 ml (10 x 5 doses)
   1 x 50 ml (1 x 25 doses), 12 x 50 ml (12 x 25 doses), 24 x 50 ml (24 x 25 doses)
   1 x 100 ml (1 x 50 doses), 12 x 100 ml (12 x 50 doses), 20 x 100 ml (20 x 50 doses)

Vials and bottles are closed with a chlorobutyl pierceable stopper sealed with an aluminium cap. In case of the mass packages the vials are located in cardboard box fitted with a grid.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.