[Version 9, 10/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Coli, emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Rotavirus suis inact.	OSU 6	RP ≥ 1*
Escherichia coli inact.	O101:K99 (F5)	RP ≥ 1*
Escherichia coli inact.	O147:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	O149:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	K85:987P (F6)	RP ≥ 1*
Escherichia coli inact.	O101:K99:F41 (F5, F41)	RP ≥ 1*

* Relative potency (determined by ELISA method) in comparison with reference serum obtained from mouse vaccinated with batch which satisfied in challenge test on target species.

Adjuvant: Emulsio olei 0.5 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.01%
Sodium chloride	
Formaldehyde (remnant from inactivation)	
Water for injection	

White or slightly pinkish oleic liquid with easy shakeable deposit.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pregnant sows and gilts)

3.2 Indications for use for each target species

For active immunization of pregnant sows and gilts, to induce maternal immunity in suckling piglets against rotavirus and *E. coli* strains expressing fimbrial adhesion factors F4, F5, F6 and F41.

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
The vaccine may rarely cause hypersensitivity. In such case, symptomatic treatment should be applied.

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

Very common (>1 animal / 10 animals treated):	- Injection site swelling*

* They resolve spontaneously within two weeks after vaccination.

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 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

Can be use during 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 route and dosage

Dose - 2 ml, intramuscularly (into the neck behind the ear).
Basic vaccination:
Sows and gilts - administration of 2 injections within an interval of 2 to 4 weeks; the second injection at the latest 2 weeks prior to the expected labour.
Revaccination:
During subsequent pregnancies: Administration of 1 injection (2 ml) 4 to 2 weeks prior to expected labour.

Shake the content of the vial before use.

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

A double vaccination dose has no side-effects on the target animals other than those specified in section 4.6

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 period(s)

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 **ATCvet code**: QI 09AL02

The vaccine contains selected serotypes of *E. coli* (O147:K88 ab, O149:K88 ac, O101:K99, 987P and O101:K99:F41). The protective fimbria antigens on these strains elicit colostral antibodies that prevent adhesion of the enterotoxigenic E. coli (ETEC) to the intestinal mucosa and thereby prevent the toxic action of the enterotoxin on the mucosa. The vaccine contains also an inactivated porcine rotavirus type A which elicits neutralizing antibodies to pathogenic Rotavirus.

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: 10 hours

5.3 Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Protect from light.
Store in a dry place.

5.4 Nature and composition of immediate packaging

The vaccine is shipped in glass vials 10 ml hydrolytic class I. or in 50 ml and 100 ml glass vials hydrolytic class II. or in 60 ml, 120 ml and 250 ml plastic bottles closed with a rubber stopper for perforation and sealed with an aluminium or flip-off cap.
Vials with the vaccine are enclosed in cardboard boxes. Each package contains an approved Package Insert. The vials in wholesale packaging are enclosed in cardboard box with a grid. The plastic box is used for package 10 × 10ml.

Package size:
1 × 10 ml, 10 × 10 ml
1 × 50 ml
1 × 100 ml
1 × 250 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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. MARKETING AUTHORISATION HOLDER

Kernfarm B.V.

7. MARKETING AUTHORISATION NUMBER

To be completed in the national phase

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: To be completed in the national phase

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

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

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Coli, emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Composition of one vaccination dose (2 ml):

Rotavirus suis inact.	OSU 6	RP ≥ 1*
Escherichia coli inact.	O101:K99 (F5)	RP ≥ 1*
Escherichia coli inact.	O147:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	O149:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	K85:987P (F6)	RP ≥ 1*
Escherichia coli inact.	O101:K99:F41 (F5, F41)	RP ≥ 1*

* Relative potency (determined by ELISA method) in comparison with reference serum obtained from mouse vaccinated with batch which satisfied in challenge test on target species.

3. PACKAGE SIZE

1 × 10 ml
10 × 10 ml
1 × 50 ml
1 × 100 ml
1 × 250 ml

4. TARGET SPECIES

Target species: Pigs (pregnant sows and gilts).

5. INDICATION

6. ROUTE OF ADMINISTRATION

Intramuscular

7. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

8. EXPIRY DATE

EXP:
Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Store in a dry place.

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

Kernfarm B.V.

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial/plastic bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Coli, emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Composition of one vaccination dose (2 ml):

Rotavirus suis inact.	OSU 6	RP ≥ 1*
Escherichia coli inact.	O101:K99 (F5)	RP ≥ 1*
Escherichia coli inact.	O147:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	O149:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	K85:987P (F6)	RP ≥ 1*
Escherichia coli inact.	O101:K99:F41 (F5, F41)	RP ≥ 1*

* Relative potency (determined by ELISA method) in comparison with reference serum obtained from mouse vaccinated with batch which satisfied in challenge test on target species.

3. TARGET SPECIES

Target species: Pigs (pregnant sows and gilts).

4. ROUTE OF ADMINISTRATION

Intramuscular

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. EXPIRY DATE

EXP:
Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Store in a dry place.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

Glass vial/plastic bottle / 10 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Rota Coli

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Composition of one vaccination dose (2 ml):

Rotavirus suis inact.	OSU 6	RP ≥ 1
E. coli inact.	O101:K99 (F5)	RP ≥ 1
E. coli inact.	O147:K88 (F4)	RP ≥ 1
E. coli inact.	O149:K88 (F4)	RP ≥ 1
E. coli inact.	K85:987P (F6)	RP ≥ 1
E. coli inact.	O101:K99:F41 (F5, F41)	RP ≥ 1

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP:

Once opened use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FIXR Rota Coli, emulsion for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:

Rotavirus suis inact.	OSU 6	RP ≥ 1*
Escherichia coli inact.	O101:K99 (F5)	RP ≥ 1*
Escherichia coli inact.	O147:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	O149:K88 (F4)	RP ≥ 1*
Escherichia coli inact.	K85:987P (F6)	RP ≥ 1*
Escherichia coli inact.	O101:K99:F41 (F5, F41)	RP ≥ 1*

* Relative potency (determined by ELISA method) in comparison with reference serum obtained from mouse vaccinated with batch which satisfied in challenge test on target species.

Adjuvans: Emulsio olei 0.5 ml

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	0.01%

White or slightly pinkish oleic liquid emulsion for injection.

3. Target species

Pigs (pregnant sows and gilts).

4. Indications for use

For active immunization of pregnant sows and gilts, to induce maternal immunity in suckling piglets against rotavirus and *E. coli* strains expressing fimbrial adhesion factors F4, F5, F6 and F41.

5. Contraindications

None.

6. Special warnings

Special warnings

Vaccinate healthy animals only.

Special precautions for safe use in the target species

The vaccine may rarely cause hypersensitivity. In such case, symptomatic treatment should be applied.

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.

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):
A double vaccination dose has no side-effects on the target animals other than those specified in "Adverse events"

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

7. Adverse events

Very common (>1 animal / 10 animals treated):	- Injection site swelling*

* They resolve spontaneously within two weeks after vaccination.

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 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

Dose - 2 ml, intramuscularly (into the neck behind the ear).
Basic vaccination:
Sows and gilts - administration of 2 injections within an interval of 2 to 4 weeks; the second injection at the latest 2 weeks prior to the expected labour.
Revaccination:
During subsequent pregnancies: Administration of 1 injection (2 ml) 4 to 2 weeks prior to expected labour.

9. Advice on correct administration
Shake the content of the vial before use.

10. Withdrawal periods
Zero days

11. Special storage precautions
Keep out of the sight and reach of children.
Store and transport refrigerated (2°C - 8°C).
Protect from light.
Store in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the immediate packaging: 10 hours

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. .

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

The product is supplied in packages of 1 × 10 ml, 10 × 10 ml, 1 × 50 ml, 1 × 100 ml and 1 × 250 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last approved

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 and contact details to report suspected adverse events
Kernfarm B.V.
De Corridor 14D

3621 ZB Breukelen
The Netherlands
Telephone: +31 (0)346 785 139

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

17. Other information