[Version 9, 03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Coli emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated *Escherichia coli*, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated	RP ≥ 1
Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated	RP ≥ 1

Relative potency (RP) is determined in comparison with reference serum obtained from animals vaccinated with a batch which complied with the challenge test in the target species.

Adjuvant:

Montanide ISA 25 VG 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**
Formaldehyde 35%	max 0.01 ml
Thiomersal	0.2 mg
Sodium chloride	
Water for injections	

White to greyish milky liquid, a small amount of sediment is allowed.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pregnant sows and gilts).

3.2 Indications for use for each target species

For the passive immunization of piglets by active immunization of pregnant sows/gilts. The suckling piglets are passively protected against the antigens contained in the vaccine (*E. coli* 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
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

Pigs (pregnant sows and gilts):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Elevated temperature[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[3].

1 Resolve spontaneously within two weeks after vaccination.
2 Usually does not exceed 1.5 °C and disappears spontaneously within 4 days
3 Symptomatic treatment should be applied.

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 used 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

For intramuscular use.
One dose of vaccine is 2 ml.
Shake the content of the vial before use.

Basic vaccination: 2 x 1 dose should be applied to sows and gilts. The first dose not later than 5 weeks before the expected delivery, the second dose 2-3 weeks before the expected delivery.

Revaccination: 1 dose 2–3 weeks before each next expected delivery. The basic vaccination shall again be performed if the interval between two subsequent deliveries exceeds 8 months.

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

After a twofold overdose no adverse effects other than those specified in section 3.6 have been observed.

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 ATC vet code: QI09AB02

The vaccine contains selected *E. coli* F4, F5, F6 and F41 serotypes enteropathogenic to suckling piglets containing protective fimbria antigens. After being applied intramuscularly into the body of a vaccinated individual, the antigens contained in the vaccine activate the immune system and induce specific antibody production.
Piglets are protected against the disease for the period of suckling from an immunised mother.

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)
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Glass vial (hydrolytic type I) containing 10 ml (5 doses), glass vial (hydrolytic type II) containing 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) or HDPE vial containg 100 ml (50 doses). Vials are closed with a rubber stopper and sealed with an aluminium cap.

Package sizes:
Carton box containing 1 vial of 5, 10, 25 or 50 doses.

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(S)

{to be completed nationally}

8 DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY {to be completed nationally}

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

DD/MM/YYYY {to be completed nationally}

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)

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Coli emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:

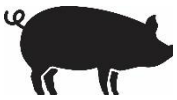
Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated *Escherichia coli*, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated	RP ≥ 1
Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated	RP ≥ 1

3. PACKAGE SIZE

1 x 5 doses
1 x 10 doses
1 x 25 doses
1 x 50 doses

4. TARGET SPECIES

Pigs (pregnant sows and gilts).



5. INDICATION(S)

6. ROUTE OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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)

{to be completed nationally}

15. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials: 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Coli

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Per dose of 2 ml:

Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated *Escherichia coli*, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated	RP ≥ 1
Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated	RP ≥ 1

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE vial: 100 ml (50 doses)
Glass vial: 100 ml (50 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR Coli emulsion for injection

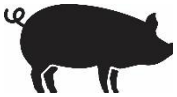
2. STATEMENT OF ACTIVE SUBSTANCES

Per dose of 2 ml:

Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated *Escherichia coli*, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated	RP ≥ 1
Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated	RP ≥ 1

3. TARGET SPECIES

Pigs (pregnant sows and gilts.



4. ROUTE OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

7. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

FIXR Coli emulsion for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:

Escherichia coli, serotype O147:K88 (fimbrial adhesin F4ab), Inactivated *Escherichia coli*, serotype O149:K88 (fimbrial adhesin F4ac), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesin F5), Inactivated	RP ≥ 1
Escherichia coli, serotype O101:K99 (fimbrial adhesins F5 and F41), Inactivated	RP ≥ 1
Escherichia coli, serotype K85:987P (fimbrial adhesin F6), Inactivated	RP ≥ 1

Relative potency (RP) is determined in comparison with reference serum obtained from animals vaccinated with a batch which complied with the challenge test in the target species.

Adjuvant:

Montanide ISA 25 VG:	0.5 ml

Excipients:

Formaldehyde solution 35% :	max 0.01 ml
Thiomersal:	0.2 mg

White to greyish milky liquid, a small amount of sediment is allowed.

3. Target species

Pigs (pregnant sows and gilts)

4. Indications for use

For the passive immunization of piglets by active immunization of pregnant sows/gilts. The suckling piglets are passively protected against the antigens contained in the vaccine (*E. coli* F4, F5, F6 and F41).

5. Contraindications

None.

6. Special warning(s)

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 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.

Pregnancy:
Can be used during 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:
After a twofold overdose no adverse effects other than those described in the section "Adverse events" have been observed.

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

7. Adverse events

Pigs (pregnant sows and gilts):

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Elevated temperature[2]
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[3].

1 Resolve spontaneously within two weeks after vaccination.
2 Usually does not exceed 1.5 °C and disappears spontaneously within 4 days
3 Symptomatic treatment should be applied.

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, route and method of administration

For intramuscular use.
One dose of vaccine is 2 ml.

Basic vaccination: 2 x 1 dose should be applied to sows and gilts. The first dose not later than 5 weeks before the expected delivery, the second dose 2-3 weeks before the expected delivery.

Revaccination: 1 dose 2–3 weeks before each next expected delivery. The basic vaccination shall again be performed if the interval between two subsequent deliveries exceeds 8 months.

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)
Do not freeze.
Protect from light.

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 hours.

12. Special precautions for the 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.
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

{to be completed nationally}

Carton box containing 1 vial of 5, 10, 25 or 50 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/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 and contact details to report suspected adverse events:
Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands
Telephone: +31650638375

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