[Version 9,10/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR APP 2,9,11 emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:

Inactivated strains of:

Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

*RP = Relative potency (ELISA) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.

Adjuvant:

Montanide ISA 35 VG	0.20 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	0.1 mg
Formaldehyde	max. 1.0 mg
Sodium chloride	
Water for injection	

Milky liquid of light grey to white colour, small amount of sediment dispersing after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for each target species

For active immunisation of fattening pigs from 6 weeks of age onwards to reduce lung lesions and to reduce colonisation of the respiratory tract by *Actinobacillus pleuropneumoniae* – the causative agent of pleuropneumonia in pigs.

Onset of immunity: 3 weeks after complete vaccination
Duration of immunity: 20 weeks after complete vaccination

3.3 Contraindications

Do not use in case of concurrent acute or pyrexial disease.

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 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 reactions (frequency and seriousness)

Common (1 to 10 animals / 100 animals treated):	- Injection site reaction* (reddish swelling, induration) - Elevation of body temperature**

* with a size of 10 cm which disappears spontaneously within 3 - 14 days.
** temporarily by 1.0 °C

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

Pregnancy and lactation:
Do not use during the pregnancy and lactation.

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

Before use, allow the vaccine to reach room temperature of 15 to 25 °C and shake well.

Administration route: Intramuscular, preferably to the paraauricular area.

Vaccination: Piglets from the age of 6 weeks are vaccinated with a dose of 1.0 ml. Revaccination is performed in 3 weeks with the same dose.

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

Following the administration of a double dose of the vaccine temporary elevation of body temperature up to 1.5 °C may occur in some of the animals. No other adverse reactions than those described in section 4.6 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

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB07

The vaccine contains inactivated whole-cell antigens of *Actinobacillus pleuropneumoniae* s.2, s.9 and s.11 and toxoids APX I, APX II and APX III. These antigens after parenteral administration cause production of specific antibodies, which help to protect against the consequences of field infection by *Actinobacillus pleuropneumoniae*.

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 in a refrigerator (2 °C – 8 °C).
Do not freeze.

5.4 Nature and composition of immediate packaging

The vaccine is presented:

in glass injection vials of hydrolytic class I:	10-ml vial with a content of 10 ml
in glass injection vials of hydrolytic class II:	50-ml vial with a content of 50 ml
	100-ml vial with a content of 100 ml
in plastic injection vials:	15-ml vial with a content of 10 ml
	60-ml vial with a content of 50 ml

	120-ml vial with a content of 100 ml
in plastic bottles:	250-ml bottle with a content of 250 ml

Vials or bottles are hermetically closed with a rubber stopper for perforation and an aluminium seal and placed to paper cartons or in plastic box with 10 wells.
Package Leaflet is a part of each packaging.
Pack sizes: 1 x 10 ml, 10 x 10 ml, 1 x 50 ml, 1 x 100 ml, 1 x 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 nationally.

8. DATE OF FIRST AUTHORISATION

DD/MM/YYYY

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

Cardboard box 1×10 ml (1 x 50 ml, 1 x 100 ml, 1 x 250 ml)
Plastic box with cover (shawl etiquette): 10×10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR APP 2,9,11 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:
Active substances:

Inactivated strains of:

Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

*RP = Relative potency (ELISA) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.

3. PACKAGE SIZE

1 x 10 ml (1 x 50 ml, 1 x 100 ml, 1 x 250 ml)
10×10 ml

4. TARGET SPECIES

Pigs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use, best to the paraauricular area.

7. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
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

Kernfarm B.V.

14. MARKETING AUTHORISATION NUMBER

To be completed nationally.

15. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass or plastic injection vial (50 ml, 100 ml)
Plastic bottle (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR APP 2,9,11 emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:
Active substances:
Inactivated strains of:

Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

*RP = Relative potency (ELISA) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use, best to the paraauricular area.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. EXPIRY DATE

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

7. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass or plastic injection vial (10 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR APP 2,9,11

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Each 1 ml dose contains:
Active substances:
Inactivated strains of:

Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1
Actinobacillus pleuropneumoniae serovars 9, 11	RP ≥ 1
toxoid APX I	RP ≥ 1
toxoid APX II	RP ≥ 1
toxoid APX III	RP ≥ 1

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

FIXR APP 2,9,11 emulsion for injection for pigs

2. Statement of the active substances and other ingredients

Each 1 ml dose contains:

Active substances:
Inactivated strains of:

Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

*RP = Relative potency (ELISA) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.

Adjuvant:

Montanide ISA 35 VG	0.20 ml

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Formaldehyde	max. 1.0 mg

Milky liquid of light grey to white colour, small amount of sediment dispersing after shaking.

3. Target species

Pigs.

4. Indications for use

For active immunisation of fattening pigs from 6 weeks of age onwards to reduce lung lesions and to reduce colonisation of the respiratory tract by *Actinobacillus pleuropneumoniae* – the causative agent of pleuropneumonia in pigs.
Onset of immunity: 3 weeks after complete vaccination
Duration of immunity: 20 weeks after complete vaccination.

5. Contraindications

Do not use in case of concurrent acute or pyrexial disease.

6. Special warnings

Special warnings for safe use in the target species:
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 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:
Do not use during the pregnancy and lactation.

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):
Following the administration of a double dose of the vaccine temporary elevation of body temperature up to 1.5°C may occur in some of the animals. No other adverse reactions than those described in section Adverse reactions have been observed.

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

7. Adverse events

Common (1 to 10 animals / 100 animals treated):	- Injection site reaction* (reddish swelling, induration) - Elevation of body temperature**

* with a size of 10 cm which disappears spontaneously within 3 - 14 days.
** temporarily by 1.0 °C

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.

8. Dosage for each species, route(s) and method of administration

Vaccination: Piglets from the age of 6 weeks are vaccinated with a dose 1.0 ml.
Revaccination is performed in 3 weeks with the same dose.
Administration route: Intramuscular, best to the paraauricular area.

9. Advice on correct administration

Before use, allow the vaccine to reach room temperature of 15 to 25 °C and shake well.
Do not use FIXR APP 2,9,11 emulsion for injection if you notice a visible signs of destroying of primary packaging material.

10. Withdrawal period

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.
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 container: 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers:

Pack sizes: 1 x 10 ml, 10 x 10 ml, 1 x 50 ml, 1 x 100 ml, 1 x 250 ml
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last approved

DD/MM/YYYY

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

17. Other information