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

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR PRRS inac, emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:
Porcine reproductive and respiratory syndrome virus, type 1, strain Bio-60, inactivated: RP* ≥ 1
Porcine reproductive and respiratory syndrome virus, type 2, strain Bio-61, inactivated: RP* ≥ 1

*RP = Relative potency (ELISA test) is expressed by comparing the level of antibodies in the serum of piglets with the level of antibodies in the reference serum obtained after vaccination with a vaccine batch that passed the challenge test in the target species.

Adjuvant:
Emulsigen 0.4 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	0.2 mg
Sodium chloride	
Potassium chloride	
Potassium dihydrogen phosphate	
Disodium hydrogen phosphate dodecahydrate	
Sodium hydroxide	
Water for injections	

Oily liquid of milky to pinkish colour.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (gilts and sows)

3.2 Indications for use for each target species

Active immunization of gilts and sows to reduce reproductive disorders and viremia caused by porcine reproductive and respiratory syndrome virus strains of the European clade A and the American type lineage 1 (PRRSV-1 subtype 1 clade A and PRRSV-2 lineage 1, respectively).

Onset of immunity: 3 weeks after primary vaccination.
Duration of immunity: 6 months after primary vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
The efficacy of the vaccine has not been tested in the presence of maternal antibodies to PRRSV type 1 and type 2.

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

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site reddening[1].
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site granuloma[3].

[1] Diameter up to 5 cm and resolves within 10 days. A small local reaction (granuloma) may remain that disappears without negative effects on the general health status or performance.
[2] Symptomatic treatment should be applied.
[3] Diameter up to 5 cm after frequently repeated vaccinations.

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:
The vaccine can be used from day 60 to day 70 of pregnancy (in accordance with the vaccination scheme).

Lactation:
Safety of the veterinary medicinal product has not been determined for use during 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

For intramuscular use by deep intramuscular injection into the neck behind the auricle.
One dose of vaccine is 2 ml.

Before use allow the vaccine to warm slowly to room temperature and shake thoroughly.

The animals (gilts) may be vaccinated before mating from the age of 6 months.

Primary vaccination:
Gilts - 2 x 1 dose with an interval of 2 - 3 weeks, before mating and a third dose on day 60 - 70 of gestation.
Sows - 2 x 1 dose with an interval of 2 - 3 weeks, before mating. Blanket vaccination of sows in the herd in the shortest possible time interval is recommended. A third dose is given on day 60 - 70 of gestation.

Revaccination:
Administer 1 dose (2 ml) on day 60 - 70 of each pregnancy following the primary vaccination.

The scope of immunization is at the discretion of a veterinary surgeon and depends also on the specific epizootic situation.

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

No adverse reactions other than those described 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 periods

Zero days.

4. IMMUNOLOGICAL IMFORMATION

4.1 ATCvet code: QI09AA05

Stimulation of active immunity against porcine reproductive and respiratory syndrome virus, type 1 and 2.

In PRRS infected herds, viral infection is heterogeneous and varies over time. In this context, the implementation of a vaccination program is a tool to improve the reproductive parameters and may contribute to control the disease in conjunction with sanitary measures.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
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.
Protect from light.

5.4 Nature and composition of immediate packaging

Glass (type I) or HDPE vial containing 5 doses (10 ml) .
Glass (type II) or HDPE vial containing 25 doses (50 ml) or 50 doses (100 ml).
The vials are closed with chlorobutyl rubber stoppers, sealed with aluminum caps.

Pack sizes:
Carboard box with a grid or PVC packaging with 10 vials of 5 doses.
Carboard box with 1 vial of 5, 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)

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box or PVC packaging

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR PRRS inac, emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

PRRS virus, type 1, strain Bio-60, inactivated: RP* ≥ 1
PRRS virus, type 2, strain Bio-61, inactivated: RP* ≥ 1

*RP = Relative potency (ELISA test) is expressed by comparing the level of antibodies in the serum of piglets with the level of antibodies in the reference serum obtained after vaccination with a vaccine batch that passed the challenge test in the target species.

3. PACKAGE SIZE

1 × 5 doses
10 × 5 doses
1 × 25 doses
1 × 50 doses

4. TARGET SPECIES

Pigs (gilts and sows)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTONS

Store in a refrigerator.
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 NUMBERS

{to be completed nationally}

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial: 10 ml, 50 ml,
HDPE vial: 10 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR PRRS inac

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

PRRS virus, type 1, strain Bio-60, inactivated: RP ≥ 1
PRRS virus, type 2, strain Bio-61, 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

Glass vial: 100 ml,
HDPE vial: 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR PRRS inac, emulsion for injection

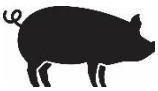
2. STATEMENT OF ACTIVE SUBSTANCES

PRRS virus, type 1, strain Bio-60, inactivated: RP* ≥ 1
PRRS virus, type 2, strain Bio-61, inactivated: RP* ≥ 1

* RP = Relative potency (ELISA test) is expressed by comparing the level of antibodies in the serum of piglets with the level of antibodies in the reference serum obtained after vaccination with a vaccine batch that passed the challenge test in the target species.

3. TARGET SPECIES

Pigs (gilts and sows)



4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
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 PRRS inac, emulsion for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:
Porcine reproductive and respiratory syndrome virus, type 1, strain Bio-60, inactivated: RP* ≥ 1
Porcine reproductive and respiratory syndrome virus, type 2, strain Bio-61, inactivated: RP* ≥ 1

*RP = Relative potency (ELISA test) is expressed by comparing the level of antibodies in the serum of piglets with the level of antibodies in the reference serum obtained after vaccination with a vaccine batch that passed the challenge test in the target species.

Adjuvant:
Emulsigen 0.4 ml

Excipients:
Thiomersal 0.2 mg

Oily liquid of milky to pinkish colour.

3. Target species

Pigs (gilts and sows).

4. Indications for use

Active immunization of gilts and sows to reduce reproductive disorders and viremia caused by porcine reproductive and respiratory syndrome virus strains of the European type clade A and the American type lineage 1 (PRRSV-1 subtype 1 clade A and PRRSV-2 lineage 1, respectively).

Onset of immunity: 3 weeks after primary vaccination
Duration of immunity: 6 months after primary vaccination

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
The efficacy of the vaccine has not been tested in the presence of maternal antibodies to PRRSV type 1 and type 2.

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:
The vaccine can be used from day 60 to day 70 of pregnancy (in accordance with the vaccination scheme).
Safety of the veterinary medicinal product has not been determined for use during 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):
No adverse reactions other than those described in the section "Adverse events" have been observed.

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

7. Adverse events

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site reddening[1].
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site granuloma[3].

[1] Diameter up to 5 cm and resolves within 10 days. A small local reaction (granuloma) may remain that disappears without negative effects on the general health status or performance.
[2] Symptomatic treatment should be applied.
[3] Diameter up to 5 cm after frequently repeated vaccinations.

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

For intramuscular use by deep intramuscular injection into the neck behind the auricle.
One dose of vaccine is 2 ml.

The animals (gilts) may be vaccinated before mating from the age of 6 months.

Primary vaccination:
Gilts - 2 x 1 dose with an interval of 2 - 3 weeks before mating and a third dose on day 60 - 70 of gestation.
Sows - 2 x 1 dose with an interval of 2 - 3 weeks before mating. Blanket vaccination of sows in the herd in the shortest possible time interval is recommended. A third dose is given on day 60 - 70 of gestation.

Revaccination:
Administer 1 dose (2 ml) on day 60 - 70 of each pregnancy following the primary vaccination.

The scope of immunization is at the discretion of a veterinary surgeon and depends also on the specific epizootic situation.

9. Advice on correct administration

Before use allow the vaccine to warm slowly to room temperature and shake thoroughly.

10. Withdrawal periods

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 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 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}

Carboard box with a grid or PVC packaging with 10 vials of 5 doses.
Carboard box with 1 vial of 5, 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