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

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR HP ERY emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substances:
Erysipelothrix rhusiopathiae (3 strains serotype 2, 1 strain serotype 1), inactivated: RP ≥ 1*
- *Erysipelothrix rhusiopathiae*, serotype 2, strain 2-64, nactivated
- *Erysipelothrix rhusiopathiae*, serotype 2, strain 2-5, inactivated
- *Erysipelothrix rhusiopathiae*, serotype 2, strain 2-II, inactivated
- *Erysipelothrix rhusiopathiae*, serotype 1,strain 203, inactivated

Haemophilus parasuis (serotypes 1, 5, 13), inactivated: RP ≥ 1*
- *Haemophilus parasuis*, serotype 1, inactivated
- *Haemophilus parasuis*, serotype 5, inactivated
- *Haemophilus parasuis*, serotype 13, inactivated

* RP = Relative potency (ELISA test) in comparison with the reference serum obtained from mice vaccinated with a batch of vaccine that complied with the challenge test in the target species.

Adjuvant:
Montanide ISA 35VG 0.2 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	≤ 1.1 mg
Sodium chloride	
Water for injections	

Grey-white milky fluid with a sediment, which is dispersed homogeneously after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pregnant sows or gilts and piglets).

3.2 Indications for use for each target species

For active immunization of piglets to reduce infection with erysipelas and *Haemophilus parasuis* (Glässer's disease) and to reduce clinical symptoms:
Onset of immunity: 21 days after vaccination
Duration of immunity: 17 weeks after vaccination

For active immunization of sows or gilts to reduce infection with erysipelas:
Onset of immunity: 21 days after vaccination
Duration of immunity: 6 months after vaccination

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 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 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 an 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 oedema[1]
Common (1 to 10 animals / 100 animals treated):	Apathy[2] Somnolence[2] Nausea[3], Vomiting[3]
Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site erythema[4] Tremor[4]

[1] 2 to5 cm in size and disappears spontaneously within 4 days.
[2] Subsides within 6 hours.
[3] After the first vaccination and disappears spontaneously within 4 hours.
[4] Disappears spontaneously within 24 hours.

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 in pregnant sows if the vaccination and revaccination are completed no later than 14 days before the expected farrowing date.

Lactation:
Not applicable.

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 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

Bring the content of the vial to room temperature (+15°C to +25°C) and shake well before use.

Method of administration:
Intramuscular use, preferably into the paraauricular region.

Immunization of piglets:
Piglets are vaccinated with a dose of **1 ml i.m.** from 6 weeks of age
Basic vaccination: 2 doses of the vaccine, administered with an interval of 3 weeks.

Immunization of sows or gilts:
Sows and gilts are vaccinated with a dose of **2 ml i.m.**
Basic vaccination: one dose of the vaccine 6-5 weeks before the expected farrowing followed by a second dose of the vaccine 2-3 weeks later, but not later than two weeks before the expected farrowing.
Revaccination: one dose of the vaccine 3-2 weeks before each subsequent farrowing.

In the event that the period between consecutive farrowings exceeds 6 months, it is necessary to follow the basic vaccination scheme.

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

After application of a double dose, tremor, apathy and somnolence may occur, which subside within a few hours. Nausea or vomiting may occur in pigs that were vaccinated immediately after food intake.

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: QI09AB

The vaccine contains inactivated bacteria which are gradually absorbed from the injection site. After administration of the antigens contained in the vaccine (*Erysipelothrix rhusiopathiae* serotypes 1 and 2, and *Haemophilus parasuis* serotypes 1, 5, 13), specific antibodies are produced by the animals which protect the immunized animals against infection with virulent *Erysipelothrix rhusiopathiae* germs and help to protect against the consequences of a field infection with *Haemophilus parasuis.* Clinical symptoms of Erysipelas and Glässer's disease are significantly reduced in vaccinated pigs. After vaccination of sows specific antibodies are produced and transferred to the offspring by the colostral route. The antibodies in the colostrum protect the offspring against clinical symptoms of Glässer's disease caused by *Haemophilus parasuis* during the whole suckling period (min. 3 weeks).

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: 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.
The vials can be stored in the dark at 20 -25°C for 10 hours after first opening.

5.4 Nature and composition of immediate packaging

HDPE vials closed with chlorobutyl rubber stoppers and sealed aluminium caps or flip off caps.

Pack sizes:
Cardboard box containing 1 vial filled with 50 or 100 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(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

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

DD/MM/YYYY

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. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR HP ERY emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Erysipelothrix rhusiopathiae (3 strains serotype 2, 1 strain serotype 1), inactivated: RP ≥ 1
Haemophilus parasuis (serotypes 1, 5, 13), inactivated: RP ≥ 1

* RP = Relative potency (ELISA test) in comparison with the reference serum obtained from mice vaccinated with a batch of vaccine that complied with the challenge test in the target species.

3. PACKAGE SIZE

1 x 50 ml
1 x 100 ml

4. TARGET SPECIES

Pigs (pregnant sows or gilts and piglets).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

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 NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label: 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR HP ERY emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Erysipelothrix rhusiopathiae (3 strains serotype 2, 1 strain serotype 1), inactivated: RP ≥ 1
Haemophilus parasuis (serotypes 1, 5, 13), inactivated: RP ≥ 1

* RP = Relative potency (ELISA test) in comparison with the reference serum obtained from mice vaccinated with a batch of vaccine that complied with the challenge test in the target species.

3. TARGET SPECIES

Pigs (pregnant sows or gilts and piglets).

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 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}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label: 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR HP ERY

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Erysipelothrix rhusiopathiae (3 strains serotype 2, 1 strain serotype 1), inactivated: RP ≥ 1
Haemophilus parasuis (serotypes 1, 5, 13), inactivated: RP ≥ 1

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FIXR HP ERY emulsion for injection for pigs

2. Composition

Each 1 ml contains:

Active substances:
Erysipelothrix rhusiopathiae (3 strains serotype 2, 1 strain serotype 1), inactivated: RP ≥ 1*
- *Erysipelothrix rhusiopathiae*, serotype 2, strain 2-64, inactivated
- *Erysipelothrix rhusiopathiae*, serotype 2, strain 2-5, inactivated
- *Erysipelothrix rhusiopathiae*, serotype 2, strain 2-II, inactivated
- *Erysipelothrix rhusiopathiae*, serotype 1, strain 203, inactivated

Haemophilus parasuis (serotypes 1, 5, 13), inactivated: RP ≥ 1*
- *Haemophilus parasuis* serotype 1, inactivated
- *Haemophilus parasuis* serotype 5, inactivated
- *Haemophilus parasuis* serotype 13, inactivated

* RP = Relative potency (ELISA test) in comparison with the reference serum obtained from mice vaccinated with a batch of vaccine that complied with the challenge test in the target species.

Adjuvant:
Montanide ISA 35VG 0.2 ml

Excipients:
Thiomersal 0.1 mg
Formaldehyde ≤ 1.1 mg
Grey-white milky fluid with a sediment, which is dispersed homogeneously after shaking.

3. Target species

Pigs (pregnant sows or gilts and piglets).

4. Indications for use

For active immunization of piglets to reduce infection with erysipelas and *Haemophilus parasuis* (Glässer's disease) and to reduce clinical symptoms:
Onset of active immunity: 21 days after vaccination
Duration of active immunity: 17 weeks after vaccination

For active immunization of sows or gilts to reduce infection with erysipelas:
Onset of immunity: 21 days after vaccination
Duration of immunity: 6 months after booster vaccination

5. Contraindications

None

6. Special warnings

Special warnings
Vaccinate only healthy animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal product contains 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 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 an involvement of finger pulp or tendon.

Pregnancy:
The vaccine can be used in pregnant sows if the vaccination and revaccination are completed no later than 14 days before the expected farrowing date.

Interaction with other medicinal products and other forms of interaction:
No data are available on the safety and efficacy of this vaccine when administered concurrently with other veterinary medicinal products. Decision about using this vaccine before or after any other veterinary medicinal product must be based on consideration of individual cases.

Overdose:
After application of a double dose, tremor, apathy and somnolence may occur, which subside within a few hours. Nausea or vomiting may occur in pigs that were vaccinated immediately after food intake.

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 oedema[1]
Common (1 to 10 animals / 100 animals treated):	Apathy[2] Somnolence[2] Nausea[3], Vomiting[3]
Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site erythema[4] Tremor[4]

[1] 2 to5 cm in size and disappears spontaneously within 4 days.
[2] Subsides within 6 hours.
[3] After the first vaccination and disappears spontaneously within 4 hours.

[4] Disappears spontaneously within 24 hours.

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(s) and method of administration

Method of administration:
Intramuscular use, preferably into the paraauricular region.

Immunization of piglets:
Piglets are vaccinated with a dose of 1 ml i.m. from 6 weeks of age
Basic vaccination: 2 doses of the vaccine, administered with an interval of 3 weeks.

Immunization of sows or gilts:
Sows and gilts are vaccinated with a dose of 2 ml i.m.
Basic vaccination: one dose of the vaccine 6-5 weeks before the expected farrowing followed by a second dose of the vaccine 2-3 weeks later, but not later than two weeks before the expected farrowing.
Revaccination: one dose of the vaccine 3-2 weeks before each subsequent farrowing.

In the event that the period between consecutive farrowings exceeds 6 months, it is necessary to follow the basic vaccination scheme.
In the event that the period between two deliveries exceeds 6 months, it is necessary to perform again the initial vaccination and revaccination.

9. Advice on correct administration

Bring the content of the vial to room temperature (+15°C to +25°C) and shake well before use.

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.
The vials can be stored in the dark at 20 -25°C for 10 hours after first opening.

Do not use this veterinary medicinal product after the 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 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

Cardboard box containing 1 vial filled with 50 or 100 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD month 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: +31 346 785 139

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