

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR RHINI suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) of vaccine contains:

Active substances:

inactivated cultures of *Pasteurella multocida* type A: 80% protection*
inactivated cultures of *Pasteurella multocida* type D: 80% protection*
inactivated cultures of *Bordetella bronchiseptica*: antibody titre not less than 32**
Pasteurella multocida toxoid: 2 µg

* upon challenge in mice

** in mice by slow agglutination test.

Adjuvant:

aluminum hydroxide gel 4.5 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
sodium ethylmercury thiosalicylate	0.2 mg
Sodium chloride	
Potassium chloride	
Bibasic sodium phosphate	
Monobasic potassium phosphate	
Water for injection	

The ready to use vaccine is a yellow-brown liquid with soft sedimentation which easily disperses after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

For the passive immunization of progeny by the active immunization of breeding females to prevent symptoms and lesions of Atrophic Rhinitis.

Onset of immunity: immediately after first intake of colostrum

Duration of immunity: has not been established

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None

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 its local representative or the national competent authority via the national reporting system. See also section 16 of 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 routes and dosage

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

Administration route: The vaccine should be inoculated subcutaneously, preferably in the fossa retroauricular, with a dose of 2 ml.

Basic vaccination: first vaccination at day 70-80 of pregnancy followed by a second dose 2-4 weeks later.

Revaccination: one dose 2-3 weeks before the expected date of farrowing

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

The administration of a double dose of vaccine did not cause particular symptoms or injuries.

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 INFORMATION

4.1 ATCvet code:

Q109AB04

Immunological properties

The active substances are constituted by inactivated *Bordetella bronchiseptica* cultures and *Pasteurella multocida* type A and type D, the bacterial agents involved in the aetiology of pig atrophic rhinitis, and from *Pasteurella multocida* toxoid. The *Pasteurella multocida* dermonecrotica toxin is the pathogenic factor that causes degenerative, progressive, and irreversible lesions of the nasal turbinates characteristics of this affection.

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: 24 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.

5.4 Nature and composition of immediate packaging

The vaccine is presented:

in glass injection vials of hydrolytic class I:	20-ml vial with a content of 20 ml (10 doses)
	100-ml vial with a content of 100 ml (50 doses)
in polypropylene bottles:	20-ml bottle with a content of 20 ml (10 doses)
	100-ml bottle with a content of 100 ml (50 doses)

Vials or bottles are hermetically closed with a rubber stopper for perforation and an aluminium seal and are placed in a cardboard box or in a polystyrene case.

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. NAME OF THE 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

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 polystyrene case

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR RHINI suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) of vaccine contains:

Active substances:

inactivated cultures of *Pasteurella multocida* type A: 80% protection*
inactivated cultures of *Pasteurella multocida* type D: 80% protection*
inactivated cultures of *Bordetella bronchiseptica*: antibody titre not less than 32**
Pasteurella multocida toxoid: 2 µg

* upon challenge in mice

** in mice by slow agglutination test.

3. PACKAGE SIZE

1 x 20 ml

1 x 100 ml

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneously, preferably in the fossa retroauricular area.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 10 hours

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C).
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 NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 100 ml

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inactivated cultures of *Pasteurella multocida* type D: 80% protection*
inactivated cultures of *Bordetella bronchiseptica*: antibody titre not less than 32**
Pasteurella multocida toxoid: 2 µg

* upon challenge in mice

** in mice by slow agglutination test.

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

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 PRECAUTIONS

Store in a refrigerator (2 °C – 8 °C).

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

Label 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR RHINI

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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inactivated cultures of *Pasteurella multocida* type D: 80% protection*
inactivated cultures of *Bordetella bronchiseptica*: antibody titre not less than 32**
Pasteurella multocida toxoid: 2 µg

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 RHINI suspension for injection for pigs

2. Composition

One dose (2 ml) of vaccine contains:

Active substances:

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inactivated cultures of *Pasteurella multocida* type D: 80% protection*
inactivated cultures of *Bordetella bronchiseptica*: antibody titre not less than 32**
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Adjuvant:

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Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
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Sodium chloride	
Potassium chloride	
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The ready to use vaccine is a yellow-brown liquid with soft sedimentation which easily disperses after shaking.

3. Target species

Pigs

4. Indications for use

For the passive immunization of progeny by the active immunization of breeding females to prevent symptoms and lesions of Atrophic Rhinitis.

Onset of immunity: immediately after first intake of colostrum

Duration of immunity: has not been established

5. Contraindications

None

6. Special warnings

Special warnings:

Vaccinate healthy animals only

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment

Not applicable

Pregnancy and lactation

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.

Major incompatibilities

Do not mix with any other veterinary medicinal product

7. Adverse events

None

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, routes and method of administration

Basic vaccination: first vaccination at day 70-80 of pregnancy followed by a second dose 2-4 weeks later.

Revaccination: one dose 2-3 weeks before the expected date of farrowing

9. Advise on correct administration

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

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.

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. 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

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The vaccine is presented:

in glass injection vials of hydrolytic class I:	20-ml vial with a content of 20 ml (10 doses)
	100-ml vial with a content of 100 ml (50 doses)
in polypropylene bottles:	20-ml bottle with a content of 20 ml (10 doses)
	100-ml bottle with a content of 100 ml (50 doses)

Vials or bottles are hermetically closed with a rubber stopper for perforation and an aluminium seal and are placed in a cardboard box or in a polystyrene case.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{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 reactions

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands
Telephone: +31 0 3 46 785 139

Manufacturer responsible for batch release:

FATRO S.p.A.
Via Emilia 285
40064 Ozzano Emilia Bologna - Italy