[Version 9,10/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MYC-VAC Emulsion for injection for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substances:

Inactivated *Mycoplasma gallisepticum*, strains MG-NEV40 and MG-NEV45: ≥ 40 HI* units.

* Mean hemagglutination inhibition units, 5 weeks after the administration of 1 dose to 3-week-old chickens.

Adjuvant:

Liquid paraffin, light 0.337 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	0.05 mg
Sorbitan monooleate	
Sodium chloride	
Potassium chloride	
Potassium Dihydrogen Phosphate	
Disodium Phosphate dodecahydrate	
Water for injection	

Visual appearance: White oily emulsion

3. CLINICAL INFORMATION

3.1 Target species

Chickens (future layers and for reproduction)

3.2 Indications for use for each target species

For active immunization of future layers and chickens for reproduction to reduce clinical symptoms and lesions of avian mycoplasmosis

Onset of immunity: 3 weeks after the second administration
Duration of immunity: 1 year after the second administration

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

None known

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

Do not use in birds in lay.

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

Subcutaneous use
Administer 0.5 ml per future layer or chicken for reproduction
The vaccine must be inoculated by the subcutaneous route in the dorsal region of the neck. The vaccine must be inoculated at 10-12 weeks of age and repeated at 18-20 weeks, prior to the start of egg production.
Bring the product to room temperature and shake the bottles well before use.

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

In overdose studies, the administration of a two-fold overdose did not cause any negative effects.

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: QI01AB03.

Inactivated vaccine to stimulate active immunity against *Mycoplasma gallisepticum.*

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 filled into polypropylene bottles (Ph. Eur.) which are closed with elastomer stoppers (Ph.Eur.) and sealed with aluminium caps.
The extractable content is 250 ml of vaccine.

Packaging:
Carton box: 1 x 250 ml polypropylene bottle
Polystyrene box: 10 x 250 ml polypropylene bottles

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 BV

7. MARKETING AUTHORISATION NUMBER(S)

Will be added in the national procedures

8. DATE OF FIRST AUTHORISATION

07/12/2021

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

Will be added in the national procedures

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

CARTON BOX / POLYSTYRENE BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MYC-VAC Emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0,5 ml dose contains:
Active substances:
Inactivated *Mycoplasma gallisepticum*, strains MG-NEV40 and MG-NEV45: ≥ 40 HI units.

3. PACKAGE SIZE

1 × 250 ml
10 × 250 ml

4. TARGET SPECIES

Chicken (future layers and for reproduction)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

EXP {month/year}
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

Will be added in the national procedures

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PAPER LABEL 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MYC-VAC Emulsion for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0,5 ml. dose contains:
Active substances:
Inactivated *Mycoplasma gallisepticum*, strains MG-NEV40 and MG-NEV45: ≥ 40 HI units.

3. TARGET SPECIES

Chicken (future layers and for reproduction)

4. ROUTES OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

EXP {month/year}
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}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FIXR MYC-VAC, emulsion for injection for chickens.

2. Composition

Each 0,5 ml dose contains:

Active substances:

Inactivated *Mycoplasma gallisepticum*, strains MG-NEV40 and MG-NEV45: ≥ 40 HI* units.

* Mean hemagglutination inhibition units, 5 weeks after the administration of 1 dose to 3-week-old chickens.

Adjuvant:

Liquid paraffin, light 0.337 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	0.05 mg

Visual appearance: White oily emulsion

3. Target species

Chicken (future layers and for reproduction)

4. Indications for use

For active immunization of future layers and chickens for reproduction to reduce clinical symptoms and lesions of avian mycoplasmosis.

Onset of immunity: 3 weeks after the second administration
Duration of immunity: 1 year after the second administration

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:
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.

Lay:
Do not use in birds in lay.

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:
In overdose studies, the administration of a two-fold overdose did not cause any negative effects.

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

7. Adverse events

None known

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: [details listed in Appendix I].

8. Dosage for each species, routes and method of administration

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Subcutaneous use
Administer 0.5 ml per future layer or chicken for reproduction
The vaccine must be inoculated by the subcutaneous route in the dorsal region of the neck. The vaccine must be inoculated at 10-12 weeks of age and repeated at 18-20 weeks, prior to the start of egg production

9. Advice on correct administration

Bring the product to room temperature and shake the bottles well before use

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 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.

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

Marketing authorisation numbers:

Will be added in the national procedures

The vaccine is filled into polypropylene bottles (Ph. Eur.) which are closed with elastomer stoppers (Ph.Eur.) and sealed with aluminium caps.
The extractable content is 250 ml of vaccine.

Packaging:
Carton box: 1 x 250 ml polypropylene bottle
Polystyrene box: 10 x 250 ml polypropylene bottles

Not all pack sizes may be marketed.
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15. Date on which the package leaflet was last revised

Will be added in the national procedures

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:

FATRO S.p.A.
Via Molini Emili, 2
25030 Maclodio Brescia - Italy