# ANNEX III

# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton box}

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MS-VAC Emulsion for injection

### 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of vaccine (0.5 ml) contains:
**Active substances:**
inactivated culture of *Mycoplasma synoviae*, strains MS-NEV1 and MS-NEV2: 1 x $10^{10}$ CFU to induce not less than 70% protection to challenge in chickens

### 3. PACKAGE SIZE

1 × 250 ml
10 × 250 ml

### 4. TARGET SPECIES

Chicken (future layers and for reproduction)

### 5. INDICATION(S)

### 6. ROUTES OF ADMINISTRATION

Subcutaneous injection

### 7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

### 8. EXPIRY DATE

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

### 9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton
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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

## 14. MARKETING AUTHORISATION NUMBERS

Vm 43877/5001

## 15. BATCH NUMBER

Lot {number}

## 16. SPECIAL WARNING(S), IF NECESSARY

## 17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

## 18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Paper label 250 ml}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MS-VAC Emulsion for injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose of vaccine (0.5 ml) contains:
**Active substances:**
inactivated culture of *Mycoplasma synoviae*, strains MS-NEV1 and MS-NEV2: 1 x $10^{10}$ CFU to induce not less than 70% protection to challenge in chickens

## 3. TARGET SPECIES

Chicken (future layers and for reproduction)

## 4. ROUTES OF ADMINISTRATION

Subcutaneous injection
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

Keep the container in the outer carton
Store in a refrigerator.
Do not freeze.
Protect from light

## 8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

## 9. BATCH NUMBER

Lot {number}

## 10. PACKAGE SIZE

250 ml

## 11. INDICATION(S)

## 12. SPECIAL WARNING(S), IF NECESSARY

## 13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet

## 14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V. To be supplied only on veterinary prescription.

## 15. MARKETING AUTHORISATION NUMBER

Vm 43877/5001

## PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MS-VAC Emulsion for injection for chickens

## 2. COMPOSITION

One dose of vaccine (0.5 ml) contains:

**Active substances:**

Inactivated culture of *Mycoplasma synoviae*, strains MS-NEV1 and MS-NEV2: 1 x $10^{10}$ CFU before inactivation, to induce not less than 70% protection to challenge in 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 | |
| Water for injection | |

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Visual appearance: White oily emulsion

## 3. TARGET SPECIES

Chicken (future layers and for reproduction)

## 4. INDICATIONS FOR USE

For active immunization of chickens to prevent mortality and reduce clinical signs (arthritis, joint swelling, lameness) and infections due to *Mycoplasma synoviae*.
Onset of immunity: 3 weeks after basic vaccination
Duration of immunity: 42 weeks)

## 5. CONTRAINDICATIONS

None.

## 6. SPECIAL WARNING(S)

Special warnings:
For Animal Treatment Only
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.

Interactions 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

Chickens (future layers and for reproduction)

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, ROUTE(S) AND METHOD OF ADMINISTRATION

0.5 ml/animal to future layers and breeders.
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 PERIOD(S)

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 container: 10 hours.

## 12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater..
Ask your veterinary surgeon how to dispose of medicines no longer required. 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

Marketing authorisation numbers:

Vm 43877/5001

The containers are made up of:
- polypropylene bottles (Ph. Eur.)

Closure
- elastomer stoppers of 29 mm diameter (Ph.Eur.)
- aluminium caps of a diameter of 29 mm.

Each individual bottle is 310 ml; its extractable contents are 250 ml of vaccine.

Pack sizes:
250 ml polypropylene bottle (500 doses) Pack of 10 x 250 ml polypropylene bottles.
Not all pack sizes may be marketed.

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

March 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk

## 16. CONTACT DETAILS

Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

## 17. OTHER INFORMATION

Approved 20 March 2023