SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MS-VAC Emulsion for injection for chickens.

2. QUALITATIVE AND QUANTITATIVE 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	

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 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

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

Chickens (future layers and for reproduction)

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

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

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.
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 synoviae

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 (one working day).

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

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.

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.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

7. MARKETING AUTHORISATION NUMBER

Vm 43877/3001

8. DATE OF FIRST AUTHORISATION

29 June 2020

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

March 2023

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)*

Approved 20 March 2023