# 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

**Excipient:**
Thiomersal 0.05 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Emulsion for injection

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Chickens (future layers and for reproduction)

### 4.2 Indications for use, specifying the 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

### 4.3 Contraindications

None

## 4.4 Special warnings for each target species

Vaccinate healthy animals only

## 4.5 Special precautions for use

i). Special precautions for use in animals

None

ii). Special precautions to be take 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 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 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

iii). Other precautions

None

## 4.6 Adverse reactions (frequency and seriousness)

Chickens (future layers and for reproduction)
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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

## 4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.

## 4.8 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.

## 4.9 Amount(s) to be administered and administration route

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.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

## 4.11 Withdrawal period(s)

Zero days.

# 5. IMMUNOLOGICAL PROPERTIES

**Pharmacotherapeutic group:**

Immunologicals for Aves, inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia)for domestic fowl.

**ATC Vet Code:**

QI01AB03.
Inactivated vaccine to stimulate active immunity against Mycoplasma synoviae

# 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Liquid paraffin, light
Sorbitan monooleate
Thiomersal
Sodium chloride
Water for injection

## 6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal products

## 6.3 Shelf life

Shelf-life of the medicinal product as packaged for sale: 24 months.
Shelf life after first opening of the immediate packaging: 10 hours (one working day).

## 6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Protect from light

## 6.5 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.

## 6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

# 7. MARKETING AUTHORISATION HOLDER

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

# 8. MARKETING AUTHORISATION NUMBER

Vm 43877/5001

# 9. DATE OF FIRST AUTHORISATION

29 June 2020

## 10. DATE OF REVISION OF THE TEXT

March 2023

Approved 20 March 2023