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 dose of vaccine (0.5 ml) contains:

Active substances:

Inactivated culture of *M. gallisepticum*, strain MG-NEV40: 1.5 x 10^{10} CFU* before inactivation to induce at least 40 HI** units in chickens.
Inactivated culture of *M. gallisepticum*, strain MG-NEV45: 1.5 x 10^{10} CFU* before inactivation, to induce at least 40 HI** units in chickens.

- Colony Forming Unit

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

Adjuvant(s):
Light liquid paraffin: 0.337 ml

Excipient(s):
Thiomersal 0.05 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White oily emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (future layers and breeders)

4.2. Indications for use, specifying the target species

For active immunisation of chickens to reduce egg production losses caused by *Mycoplasma gallisepticum*

Onset of immunity: 10 weeks after completion of the primary vaccination schedule
Duration of immunity: 42 weeks after completion of the primary vaccination schedule

A reduction of thoracic and abdominal air sac lesions caused by Mycoplasma gallisepticum was demonstrated in vaccinated birds with an onset of immunity of 4 weeks after completion of the primary vaccination schedule, however a duration of immunity has not been investigated

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to the 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

4.6 Adverse reactions (frequency and seriousness)

After the first and second vaccination a mild swelling of short duration might be very commonly observed.

After the first vaccination mild depression lasting for 2-3 days might be commonly observed.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and within 4 weeks before the start of the laying period.

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 Amounts to be administered and method of administration

Subcutaneous use.

Dose: 0.5 ml to future layers and breeders

The vaccine must be inoculated by the subcutaneous route in the dorsal region of the neck. Administer two doses of FIXR MYC-VAC separated by an interval of 8 weeks from 10 weeks of age, 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

No adverse reactions except those mentioned in section 4.6 were observed after the administration of a double dose of vaccine.

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.

ATCvet code: QI01AB03.

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

Specific antibodies are detected from 4 weeks until 42 weeks post vaccination in vaccinated animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Sorbitan monooleate
Thiomersal
Sodium chloride
Potassium chloride
Potassium Dihydrogen Phosphate

Disodium Phosphate·dodecahydrate
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: 21 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.

6.5 Nature and composition of the primary packaging

Polypropylene bottles (Ph. Eur.) with elastomer stoppers (29 mm diameter) and sealed with aluminium caps (29 mm diameter) containing 250 ml of the vaccine. One bottle in a cardboard box or ten bottles in a polystyrene box.

The extractable content is 250 ml of vaccine.

Not all pack sizes may be marketed.

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 BV
De Corridor 14D
3621 ZB Breukelen
The Netherlands

8. MARKETING AUTHORISATION NUMBER

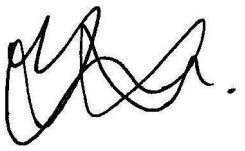
Vm 43877/5000

9. DATE OF FIRST AUTHORISATION

05 April 2023

10. DATE OF REVISION OF THE TEXT

April 2023



Approved: 05 April 2023