ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE PACKAGE

Carton Box
250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MYC-VAC emulsion for injection for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

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.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

1 x 250 ml
10 x 250 ml

5. TARGET SPECIES

Chicken (future layers and breeders)

6. INDICATION(S)

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

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous
Read the package leaflet before use

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43877/5000

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET

FIXR MG-VAC, emulsion for injection for chickens.

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Kernfarm B.V.
De Corridor 14D
3621 ZB Breukelen
The Netherlands

Manufacturer responsible for batch release:
FATRO S.p.A.
Via Molini Emili, 2
25030 Maclodio Brescia - Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR MG-VAC
Emulsion vaccine for injection for chickens.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

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

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

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).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 inform your veterinary surgeon.

7. TARGET SPECIES

Chicken (future layers and breeders)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP
Shelf life after first opening the container: 10 hours (one working day).

12. SPECIAL WARNING(S)

Special warnings for each target species
Vaccinate healthy animals only.

Special precautions for use in animals
None

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 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 and within 4 weeks before the start of the laying period.

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 (symptoms, emergency procedures, antidotes):
No adverse reactions except those mentioned in section 6 were observed after the administration of a double dose of vaccine.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

{DD/MM/YYYY}

15. OTHER INFORMATION

For animal treatment only.

To be supplied only on veterinary prescription.

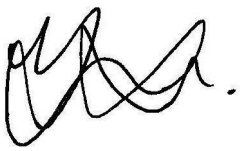
The vaccine is supplied in polypropylene bottles (Ph. Eur.) with elastomer stoppers (29 mm diameter) and sealed with aluminium caps (29 mm diameter) containing 250 ml of the vaccine.

One bottle in a cardboard box or ten bottles in a polystyrene box.
The extractable content is 250 ml of vaccine.

Pack sizes:
250 ml polypropylene bottle (500 doses)
Pack of 10 x 250 ml polypropylene bottles

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.



Approved: 05 April 2023