

LABELLING AND PACKAGE LEAFLET

LABELLING

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS

Etiquette 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR M Hyo One emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One vaccine dose (2 ml) contains:

Active substance:

Inactivated *Mycoplasma hyopneumoniae* strain 1137 RP \geq 1

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}

Once opened use by: 10 hours

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box 10×10 ml (1 x 100 ml, 1 x 250 ml)

Plastic box with cover (shawl etiquette): 10×10 ml

Etiquette 100 ml (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR M Hyo One emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One vaccine dose (2 ml) contains:

Active substance:

Inactivated *Mycoplasma hyopneumoniae* strain 1137 RP ≥ 1*

*RP = Relative potency (ELISA) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

10 x 10 ml
1 x 100 ml
1 x 250 ml

5. TARGET SPECIES

Pigs (fattening pigs)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
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 by: 10 hours

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

Protect from light.

Protect from frost.

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)

17. MANUFACTURER’S BATCH NUMBER

Batch

