

PACKAGE LEAFLET

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FIXR M Hyo One emulsion for injection for pigs

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:

Bioveta, a.s.
Komenského 212/12
Ivanovice na Hané
683 23 Czech Republic.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR M Hyo One emulsion for injection for pigs

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

One vaccine dose (2 ml) contains:

Active substance:

Inactivated *Mycoplasma hyopneumoniae* strain 1137 RP \geq 1*

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

Adjuvant:

Montanide ISA 35 VG 0.2 ml

Excipients:

Formaldehyde solution 35% max. 2 mg
Thiomersal 0.2 mg

Appearance: Milky liquid of yellowish-white to light pink colour without sediment or with small amount of sediment dispersing after shaking.

4. INDICATION(S)

For active immunization of fattening pigs from 7 days of age to reduce lung lesions caused by *Mycoplasma hyopneumoniae* - a causative agent of enzootic pneumonia in pigs.

Onset of immunity: 14 days after administration of a single dose.

In farms with high infection pressure by *Mycoplasma hyopneumoniae* where 2 doses with an interval of 3 weeks can be administered: 14 days after completion of the vaccination scheme.

Duration of immunity: 26 weeks after vaccination with a single dose.

In farms with high infection pressure by *Mycoplasma hyopneumoniae* where 2 doses with an interval of 3 weeks can be administered: 26 weeks after completion of the vaccination scheme.

5. CONTRAINDICATIONS

Do not use in case of any acute or febrile illness.

6. ADVERSE REACTIONS

Common local reactions up to 3 cm in diameter can occur after application, which disappear spontaneously within 3 days.

Very commonly animals may manifest a transient increase in body temperature max. 1 °C.

Rare hypersensitive reaction may occur. In this case, you must promptly initiate appropriate treatment.

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

Pigs (fattening pigs)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Vaccination: A 2-ml dose of the vaccine should be administered according to the following scheme:

- 1 dose should be administered to piglets from 11 days of age.
- In farms with high infection pressure by *Mycoplasma hyopneumoniae* 2 doses with an interval of 3 weeks can be administered from 7 days of age.

Selection of the vaccination scheme depends on knowing the disease incidence on a particular farm.

Method of administration: Intramuscularly, preferably into the paraauricular region.

9. ADVICE ON CORRECT ADMINISTRATION

Before use, allow the vaccine to reach room temperature of 15 to 25 °C and shake well.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Store in a refrigerator (2 °C - 8 °C).

Protect from light.

Protect from frost.

Shelf life after first opening the immediate packaging: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals

During the vaccination is necessary to avoid stressing of animals.

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 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”.

Pregnancy and lactation:

The use is not recommended during pregnancy and lactation.

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 other adverse reactions in target animals than those described in section Adverse Reactions were observed after the administration of a double dose.

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

The vaccine is presented in:

Glass injection vials of hydrolytic class I:	10-ml vial containing 10 ml
Glass injection vials of hydrolytic class II:	100-ml vial containing 100 ml
Plastic injection vials HDPE:	15-ml vial containing 10 ml
	120-ml vial containing 100 ml
Plastic bottles HDPE:	250-ml bottle containing 250 ml

The vials or bottles are hermetically closed with chlorobutyl rubber stopper and sealed with aluminium cap and are packed in a cardboard box.

Multiple packed vials are placed in a cardboard box or a plastic box with wells.

A Package Leaflet is included in each package.

Pack size: 10 x 5 doses (10 x 10 ml), 1 x 50 doses (1 x 100 ml), 1 x 125 doses (1 x 250 ml)

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.