

*[Version 8.1,01/2017]*

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FIXR M Hyo One emulsion for injection for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Emulsion for injection.

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

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pigs (fattening pigs)

### 4.2 Indications for use, specifying the target species

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.

#### **4.3 Contraindications**

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

#### **4.4 Special warnings for each target species**

Vaccinate healthy animals only.

#### **4.5 Special precautions for use**

##### 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.

#### **4.6 Adverse reactions (frequency and seriousness)**

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).

#### **4.7 Use during pregnancy, lactation or lay**

The use is not recommended during pregnancy and lactation.

#### **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 administration route**

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 parauricular region.

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

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

No other adverse reactions in target animals than those described in section 4.6 were observed after administration of a double dose.

#### **4.11 Withdrawal period(s)**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Immunologicals for suidae, inactivated bacterial vaccines - mycoplasma  
ATCvet code: QI09AB13

#### **Mechanism of action:**

The product stimulates active immunity against *Mycoplasma hyopneumoniae*, to reduce lung lesions caused by *Mycoplasma hyopneumoniae* - a causative agent of enzootic pneumonia in pigs.

#### **Environmental characteristics:**

The product contains only inactivated antigens and no living microorganisms which would be excreted and would threaten other animals or humans. The half-life of adjuvant vaccine after administration to

an animal is given by an individual animal reactivity to the injected antigenic complex. All components of the vaccine are harmlessly biodegradable in the body. The product use means no burden on the environment.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Oil emulsion Montanide ISA 35 VG

Formaldehyde solution 35%

Thiomersal

Sodium chloride

Water for injection

### **6.2 Major incompatibilities**

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

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

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

### **6.4. Special precautions for storage**

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

Protect from light.

Protect from frost.

### **6.5 Nature and composition of immediate packaging**

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.

**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(S)**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

DD/MM/YYYY

**10. DATE OF REVISION OF THE TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

