SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyogen
emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:
Active substance:
Inactivated
Mycoplasma hyopneumoniae 2940 strain: min. 5.5 EU *
Adjuvants:

Light liquid paraffin	187 µl
Escherichia coli J5 LPS	max. 38000 Endotoxin unit

Excipient:

Thiomersal	50 µg

* Mean antibody titre – expressed in *M. hyopneumoniae* ELISA Unit – obtained 28 days after the immunisation of rabbits with half of pig vaccine dose (1ml).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection
Off-white, homogeneous emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs for fattening

4.2 Indications for use, specifying the target species

For the active immunization of fattening pigs from 3 weeks of age to reduce the occurrence and severity of lung lesions caused by *Mycoplasma hyopneumoniae* infection.

Onset of immunity: 3 weeks after the vaccination
Duration of immunity: 26 weeks after vaccination

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

Not applicable.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 and 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)

On the day of vaccination a transient mean increase in body temperature of about 1.3°C is very common. In an individual pig this increase might reach 2°C, but in all cases body temperature is back to normal the next day.
A local reaction at the site of injection in the form of a swelling of a diameter up to 5 cm can be very common, which can last for three days. These reactions are of transient nature and do not need further treatment.
Immediate mild hypersensitivity-like reactions may occur uncommonly after vaccination, resulting in transient clinical signs such as vomiting.
Serious anaphylactic-type reactions (shock, recumbency) which may be fatal have been reported very rarely from post-marketing surveillance. Such reactions require prompt symptomatic 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

Not applicable.

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

Intramuscular use.
Vaccinate pigs in the side of their neck.
Administer a single dose of 2 ml from 3 weeks of age.
The data available are not sufficient to exclude the interaction of maternally derived antibodies with vaccine uptake. Interaction with maternal-derived antibodies is known and should be taken into consideration. It is recommended to delay vaccination in piglets with residual MDA at the age of 3 weeks.

Shake well before use.
Use sterile syringe and needle, respect aseptic conditions of vaccination.

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

As the vaccine is inactivated, studies investigating the safety of an overdose administration are not required.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Pig / Inactivated bacterial vaccines / mycoplasma
ATCvet code: QI09AB13
Inactivated bacterial vaccine, containing whole cell concentrate of *Mycoplasma hyopneumoniae* strain 2940. This antigen is incorporated in an adjuvant for stimulation of immunity, based on a combination of light liquid paraffin and cell free *Escherichia coli* J5 LPS. The product stimulates the development of active immunity in pigs against *Mycoplasma hyopneumoniae*.
Under experimental conditions reduction of *M. hyopneumoniae* colonization was demonstrated 44-50 days post vaccination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Light liquid paraffin
Sorbitan trioleate
Polysorbate 80
Escherichia coli J5 LPS
Thiomersal
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 15 months
Shelf life after first opening the immediate packaging: 10 hours

6.4 Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene bottle of 50, 100, 200 or 250 ml volume, sealed with rubber stopper and aluminium cap, in a cardboard box.

Pack sizes:
1x50 ml (1x25 doses)
1x100 ml (1x50 doses)
1x200 ml (1x100 doses) in 200 ml bottle
1x200 ml (1x100 doses) in 250 ml bottle
1x250ml (1x125 doses)
5x50 ml (5x25 doses)
5x100 ml (5x50 doses)
5x200 ml (5x100 doses) in 200 ml bottle
-5x200 ml (5x100 doses) in 250 ml bottle
5x250 ml (5x125 doses)

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

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

8. MARKETING AUTHORISATION NUMBER

Vm 15052/4078

9. DATE OF FIRST AUTHORISATION

11 June 2015

10. DATE OF REVISION OF THE TEXT

September 2021

Approved: 06/09/21