# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyogen emulsion for injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:
**Active substance:**
Inactivated *Mycoplasma hyopneumoniae* 2940 strain: min. 328 Elisa Units

**Adjuvants:**

Light liquid paraffin 187 µl
*Escherichia coli* J5 LPS min. 594 - max. 38000 Endotoxin unit

**Excipient:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Thiomersal | 30.6 - 58.5 µg |
| Sorbitan trioleate | |
| Polysorbate 80 | |
| Sodium chloride | |
| Potassium chloride | |
| Disodium phosphate dihydrate | |
| Potassium dihydrogen phosphate | |
| Water for injections | |

Off-white, homogeneous emulsion.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs (for fattening)

### 3.2 Indications for use for each target species

For the active immunisation 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 vaccination

Duration of immunity: 26 weeks after vaccination

## 3.3 Contraindications

None.

## 3.4 Special warnings

Vaccinate healthy animals only.

The data available are not sufficient to exclude the interaction of maternally derived antibodies against *Mycoplasma hyopneumoniae* with vaccine uptake. Interaction with maternally derived antibodies is known and should be taken into consideration. It is recommended to delay vaccination in piglets with residual MDA against *Mycoplasma hyopneumoniae* at the age of 3 weeks.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse events

Pigs (for fattening)

| | |
|---|---|
| Very common<br>(>1 animal / 10 animals treated): | Elevated temperature [1]<br>Injection site swelling [2] |
| Uncommon<br>(1 to 10 animals / 1,000 animals treated): | Hypersensitivity reaction [3] |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Anaphylactic shock [4] |

[1] Increase in body temperature (average 1.3 °C, in individual pigs up to 2 °C) on the day of vaccination, which resolves within one day.

[2] A local injection site swelling up to 5 cm in diameter, lasting up to three days. These reactions do not need further treatment.

[3] Immediate mild hypersensitivity-like reactions after vaccination, resulting in transient clinical signs such as vomiting.

[4] Serious anaphylactic-type reactions (shock, recumbency) which may be fatal. Such reactions require prompt symptomatic treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

## 3.7 Use during pregnancy, lactation or lay

Not applicable

## 3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Circovac and administered to piglets at one injection site. Vaccinate piglets from 3 weeks of age.

Onset of immunity: 3 weeks after vaccination when mixed with Circovac
Duration of immunity: 23 weeks when mixed with Circovac.

In case of mixing with Circovac, slight and transient local reactions may occur very commonly after the administration, mainly swelling (0.5 cm - 5 cm), mild pain and redness as well as in some cases oedema. These reactions resolve spontaneously

within maximum 4 days. Transient lethargy may occur very commonly on the day of vaccination which resolves spontaneously within 1-2 days. An increase in individual

rectal temperature of up to 2.5 °C may occur commonly lasting less than 24 hours.
The above adverse reactions were observed in clinical studies.

The product literature of Circovac should be consulted before mixed administration.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except when mixed with Circovac. 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.

## 3.9 Administration routes and dosage

Intramuscular injection of one dose of 2 ml.

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

**When Hyogen is used alone:**

Vaccinate pigs in the side of their neck.
Administer a single dose of 2 ml from 3 weeks of age.

**When Hyogen is mixed with Circovac:**

The mixed use is restricted to the 100 doses (200 ml) presentations of Hyogen and to the 100 doses presentations (50 ml of reconstituted vaccine) of Circovac.

Piglets from 3 weeks of age:

| Hyogen | Circovac |
|---|---|
| 100 doses (200 ml of vaccine) in 250 ml bottle | 100 doses for piglets (50 ml of reconstituted suspension + emulsion) |

Vaccine devices should be used under aseptic conditions and in accordance with the device instructions provided by the manufacturer.
Prepare Circovac by vigorously shaking the vial of antigen suspension and injecting its content into the vial of emulsion containing adjuvant.
Mix 200 ml of Hyogen and 50 ml of Circovac and shake gently until a homogeneous white emulsion is obtained.
Administer one 2.5 ml dose of the mixture by intramuscular injection, in the side of the neck.
Use the entire vaccine mixture immediately after mixing.

## 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 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* colonisation was demonstrated 44-50 days post vaccination.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except Circovac.

### 5.2 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

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

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

1x50 ml (1x25 doses),
1x100 ml (1x50 doses),
1x200 ml (1x100 doses) in 200 ml bottle,
1x200 ml (1x100 doses) in 250 ml bottle,
1x250 ml (1x125 doses),

5x50 ml (5x25 doses),
5x100 ml (5x50 doses),
5x200 ml (5x100 doses) in 200 ml bottles,
5x200 ml (5x100 doses) in 250 ml bottles
5x250 ml (5x125 doses).

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste>.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd

## 7. MARKETING AUTHORISATION NUMBER

Vm 15052/3013

## 8. DATE OF FIRST AUTHORISATION

11 June 2015

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2024

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Approved 28 April 2024