PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1x50, 1x100, 1x 200/200, 1x 200/250, 1x250, 5x50, 5x100, 5x200/200, 5x200/250, 5x250 ml carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyogen emulsion for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (2 ml) contains: *Mycoplasma hyopneumoniae* 2940 strain: 328 ELISA Units
Oil adjuvant
Thiomersal 50 µg

3. PACKAGE SIZE

50 ml (25 doses)
100 ml (50 doses)
200 ml (100 doses) in 200 ml bottle
200 ml (100 doses) in 250 ml bottle
250 ml (125 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)

4. TARGET SPECIES

Pigs for fattening.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

EXP { mm/yyyy }
Once opened, use by 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2□C – 8□C).
Do not freeze.

Keep the bottle tightly closed in order to protect from light and moisture.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5050

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V ('Veterinary medicinal product subject to prescription') PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100, 200 or 250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyogen emulsion for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (2 ml) contains: *Mycoplasma hyopneumoniae* 2940 strain: 328 ELISA Units
Oil adjuvant
Thiomersal 50 µg

3. TARGET SPECIES

Pigs for fattening.

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

EXP { mm/yyyy }
Once opened, use by 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2□C – 8□C).
Do not freeze.

Keep the bottle tightly closed.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Sante Animale

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

12. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
POM-V (‘Veterinary medicinal product subject to prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyogen emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Mycoplasma hyopneumoniae 2940 strain: 328 ELISA units / dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP { mm/yyyy }
Once opened use by 10 hours.

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyogen Emulsion for Injection for Pigs

2. 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:
Thiomersal 50 µg

Off-white, homogeneous emulsion.

3. TARGET SPECIES

Pigs for fattening

4. INDICATIONS FOR USE

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

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

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.
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.

Pregnancy and lactation:
Not applicable.

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.

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

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.

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.

Overdose (symptoms, emergency procedures, antidotes):
As the vaccine is inactivated, studies investigating the safety of an overdose administration are not required.

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

7. ADVERSE EVENTS

Very common (>1 animal / 10 animals treated):	Elevated temperature* Injection site swelling**
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypersensitivity reaction*** Vomiting***
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic shock**** Recumbency****

*On the day of vaccination a transient mean increase in body temperature of about 1.3oC is very common. In an individual pig this increase might reach 2oC, 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. 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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

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

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

9. ADVICE ON CORRECT ADMINISTRATION

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

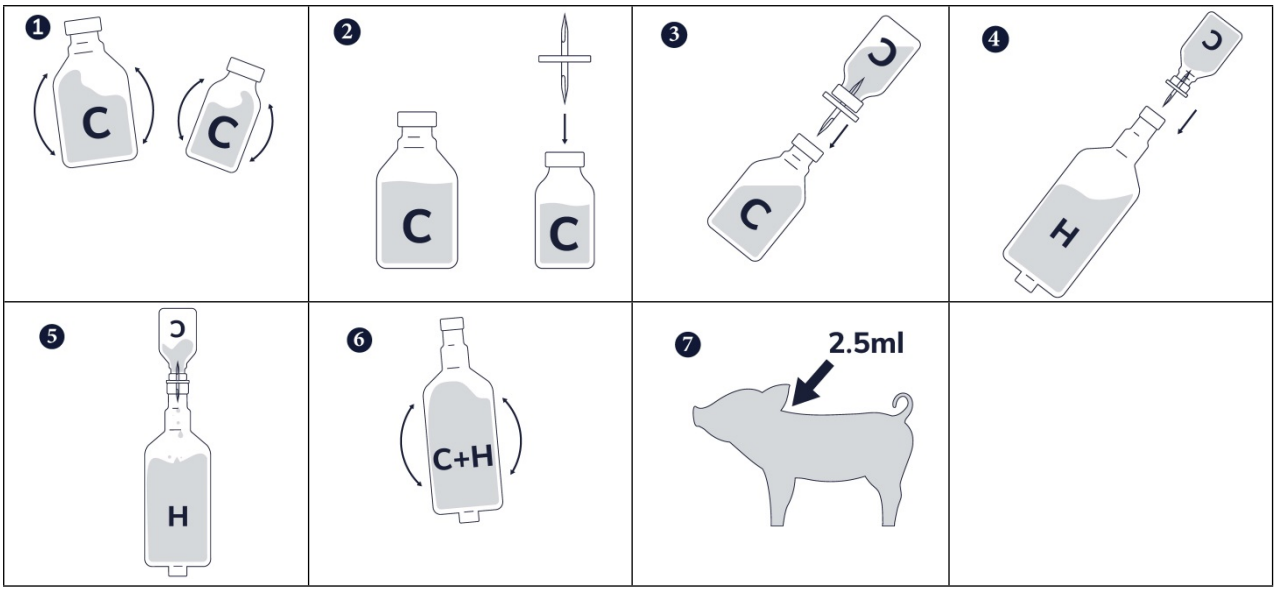
When Hyogen is mixed with Circovac:

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.
Step 1.-3. Prepare Circovac (C) by vigorously shaking the vial of antigen suspension and injecting its content into the vial of emulsion containing adjuvant.
Step 4.-6. Mix 200 ml of Hyogen (H) and 50 ml of Circovac and shake gently until a homogeneous white emulsion is obtained.
Step 7. 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.



10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2□C – 8□C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.
The expiry date refers to the last day of that month.
Shelf life after first opening the container: 10 hours

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 14966/5050

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.

Pack sizes:
50, 100, 200 or 250 ml in polyethylene bottle, 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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

01628 334056
technicalandpvuk-group@ceva.com

Manufacturer responsible for batch release:

Ceva-Phylaxia Co. Ltd.
1107 Budapest Szállás u. 5.
Hungary

17. OTHER INFORMATION

Immunological properties:
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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

POM-V ('Veterinary medicinal product subject to prescription')
For animal treatment only.

Gavin Hall
Approved: 10 October 2025