

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

1x50, 1x100, 1x 200, 1x250, 5x50, 5x100, 5x200, 5x250 ml carton box  
100, 200 or 250 ml bottle

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Hyogen emulsion for injection for pigs

**2. STATEMENT OF ACTIVE SUBSTANCES**

One dose (2 ml) contains: *Mycoplasma hyopneumoniae* 2940 strain: 5.5 ELISA Units  
Oil adjuvant  
Thiomersal 50 µg

**3. PHARMACEUTICAL FORM**

Emulsion for injection

**4. PACKAGE SIZE**

50 ml  
100 ml  
200 ml  
250 ml  
5x50 ml  
5x100 ml  
5x200 ml  
5x250 ml

**5. TARGET SPECIES**

Pigs for fattening.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use.  
Read the package leaflet before use and disposal.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: Zero days.

**9. SPECIAL WARNING(S), IF NECESSARY**

Accidental injection is dangerous.

**10. EXPIRY DATE**

EXP {month/year}

Once opened, use by 10 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated (2°C – 8°C).

Do not freeze.

Protect from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

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

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

<b>16. MARKETING AUTHORISATION NUMBER</b>
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Vm 15052/4078

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Lot {number}

**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. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

*Mycoplasma hyopneumoniae* 2940 strain: 5.5 ELISA unit / dose

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

50 ml

**4. ROUTE(S) OF ADMINISTRATION**

IM

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period: Zero days.

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}  
Once opened use by 10 hours.

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
Hyogen 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:

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

Manufacturer responsible for batch release:

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

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Hyogen emulsion for injection for pigs

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

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).

Off-white, homogeneous emulsion.



#### **4. INDICATION(S)**

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. ADVERSE REACTIONS**

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).

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 for fattening

## **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.

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.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Shake well before use.

Use sterile syringe and needle, respect aseptic conditions of vaccination.

## **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.

Shelf life after first opening the container: 10 hours

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

Vaccinate healthy animals only.

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.

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.

Duration of immunity: at least 23 weeks when mixed with Circovac.

In case of mix with Circovac, commonly, an increase in individual rectal temperature of up to 2.5°C lasting less than 24 hours may occur. Read also the product information of Circovac before mixed use. Slight and transient local reactions may occur after the administration, mainly swelling and redness as well as in some cases oedema. These reactions resolve spontaneously within maximum 4 days.

**When Hyogen is mixed with Circovac:**

Piglets from 3 weeks of age:

<b>Hyogen</b>	<b>Circovac</b>
100 doses (200 ml of vaccine)	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 shaking vigorously 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 deep intramuscular injection.

Use the entire vaccine mixture immediately after mixing. Read also the product information of Circovac before use.

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.

Incompatibilities:

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

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

October 2022

**15. 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.

Pack sizes:

50, 100, 200 or 250 ml in polyethylene bottle. 1x50 ml, 1x100 ml, 1x200 ml, 1x250 ml, 5x50 ml, 5x100 ml, 5x200 ml or 5x250 ml in a cardboard box.

Not all pack sizes may be marketed.

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

Approved 13 October 2022

