

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

## **A. LABELLING**

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

**1x50, 1x100, 1x 200 /200, 1x 200/250, 1x250, 5x50, 5x100, 5x200/200, 5x200/250, 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 (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 bottle  
5x200 ml (5x100 doses) in 250 ml bottle  
5x250 ml (5x125 doses)

**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  
Unit 3, Anglo Office Park  
White Lion Road  
Amersham  
Buckinghamshire  
HP7 9FB

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 15052/4078

**17. MANUFACTURER'S BATCH NUMBER**

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  
Unit 3, Anglo Office Park  
White Lion Road  
Amersham  
Buckinghamshire  
HP7 9FB

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:

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.

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.

**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**

May 2021

**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.

50, 100, 200 or 250 ml in polyethylene bottle, 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,  
1x250 ml (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.

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

Approved: 06/09/21

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending from the end of the signature.