ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MHYOSPHERE PCV ID emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.2 ml contains:

Active substance:

Inactivated recombinant *Mycoplasma hyopneumoniae*^{cpPCV2}, strain Nexhyon:

- *Mycoplasma hyopneumoniae* *RP* ≥ 1.3*
- *Porcine circovirus type 2 (PCV2) capsid protein* *RP* ≥ 1.3*

* Relative Potency determined by ELISA.

Adjuvant:
Light mineral oil 42.40 mg

Qualitative composition of excipients and other constituents
Disodium edetate (EDTA)
Disodium phosphate dodecahydrate
Manganese sulfate monohydrate
Poloxamer 407
Polysorbate 80
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Sodium hydroxide
Sorbitan mono-oleate
Water for injections

White homogeneous emulsion after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

For the active immunisation of pigs:

- to reduce lung lesions associated with porcine enzootic pneumonia caused by *Mycoplasma hyopneumoniae*. Also, to reduce the incidence of these lesions (as observed in field studies).
- to reduce viraemia, virus load in lungs and lymphoid tissues and the duration of the viraemic period associated with diseases caused by Porcine circovirus type 2 (PCV2). Efficacy against PCV2 genotypes a, b and d has been demonstrated in field studies.

- to reduce culling rate and the loss of daily weight gain caused by *Mycoplasma hyopneumoniae* and/or PCV2 related diseases (as observed at 6 months of age in field studies).

Mycoplasma hyopneumoniae:
Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 23 weeks after vaccination.

Porcine circovirus type 2:
Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 22 weeks after vaccination.

In addition, a reduction in nasal and faecal shedding and the duration of nasal excretion of PCV2 was demonstrated in animals challenged at 4 weeks and at 22 weeks after vaccination.

3.3 Contraindications

Do not use in case of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

3.4 Special warnings

Vaccinate healthy animals only.

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:

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:

Very common (> 1 animal / 10 animals treated):	Injection site inflammation[1] Depression[2]
Common (1 to 10 animals / 100 animals treated):	Injection site inflammation[3] Elevated temperature[4]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction[5]

[1]Mild transient local reactions consisting of non-painful skin inflammations, of less than or equal to 3 cm in diameter.
[2]A slight depression, which subsides in less than 24 hours without treatment is very commonly observed.
[3]Moderate inflammation (between 3-5 cm) at the inoculation site is observed from 4 hours post-vaccination to day three. These local reactions can be observed during the first week after vaccination and last for 1 to 5 days. One or two weeks later, these local reactions can reappear lasting for 1 to 7 days. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.
[4]Slight transient increase in body temperature (mean 0.6 ºC, in individual pigs less than 2 ºC) that subsides spontaneously within 48 hours without treatment.
[5]Anaphylactic-type reactions (e.g. vomiting, circulatory disorders, dyspnoea) which might be life-threatening, may occur in some sensitive animals. Under these circumstances, appropriate symptomatic treatment should be administered.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

For intradermal use.

Before use allow the vaccine to reach room temperature.
Shake well before use.
Administer one dose of 0.2 ml to pigs from 3 weeks of age onwards by intradermal administration at the sides of the neck using a suitable needle-free device able to administer 0.2 ml doses per shot (with an injection stream diameter of 0.25-0.30 mm and a peak force of injection of 0.9-1.3 N).

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

None known.

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: QI09AL08

To stimulate active immunity against *Mycoplasma hyopneumoniae* and Porcine circovirus type 2 in pigs.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

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: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the container in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

20 ml PET vials (containing 10 ml) with 50 doses and 50 ml PET vials with 100 doses (20 ml), 125 doses (25 ml) or 250 doses (50 ml).
The vials are closed with a chlorobutyl rubber stopper and an aluminium cap.

Pack sizes:
Cardboard box with 1 PET vial of 50 doses (10 ml).
Cardboard box with 1 PET vial of 100 doses (20 ml).
Cardboard box with 1 PET vial of 125 doses (25 ml).
Cardboard box with 1 PET vial of 250 doses (50 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/259/001-004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/09/2020

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

{DD/MM/YYYY}

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 1 PET vial of 50 doses (10 ml)
Cardboard box with 1 PET vial of 100 doses (20 ml)
Cardboard box with 1 PET vial of 125 doses (25 ml)
Cardboard box with 1 PET vial of 250 doses (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MHYOSPHERE PCV ID emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 0.2 ml contains:

Inactivated recombinant *Mycoplasma hyopneumoniae*^{cpPCV2}, strain Nexhyon:

- *Mycoplasma hyopneumoniae* *RP* ≥ 1.3*
- *Porcine circovirus type 2 (PCV2) capsid protein* *RP* ≥ 1.3*

* Relative Potency determined by ELISA.

3. PACKAGE SIZE

50 doses (10 ml)
100 doses (20 ml)
125 doses (25 ml)
250 doses (50 ml)

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the container in the outer carton in order to 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

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/20/259/001 (50 doses (10 ml))
EU/2/20/259/002 (100 doses (20 ml))
EU/2/20/259/003 (125 doses (25 ml))
EU/2/20/259/004 (250 doses (50 ml))

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 50, 100, 125 or 250 doses.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MHYOSPHERE PCV ID

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose of 0.2 ml contains:

Inactivated recombinant *Mycoplasma hyopneumoniae*^{cpPCV2}, strain Nexhyon:

- *Mycoplasma hyopneumoniae* *RP ≥ 1.3*
- *Porcine circovirus type 2 (PCV2) capsid protein* *RP ≥ 1.3*

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately.

5. PACKAGE SIZE

50 doses (10 ml)
100 doses (20 ml)
125 doses (25 ml)
250 doses (50 ml)

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

MHYOSPHERE PCV ID emulsion for injection for pigs

2. Composition

Each dose of 0.2 ml contains:

Active substance:

Inactivated recombinant *Mycoplasma hyopneumoniae*^{cpPCV2} strain Nexhyon:

- *Mycoplasma hyopneumoniae* *RP* ≥ 1.3*
- *Porcine circovirus type 2 (PCV2) capsid protein* *RP* ≥ 1.3*

* Relative Potency determined by ELISA.

Adjuvant:
Light mineral oil 42.40 mg

White homogeneous emulsion after shaking.

3. Target species

Pigs.

4. Indications for use

For the active immunisation of pigs:
- to reduce lung lesions associated with porcine enzootic pneumonia caused by *Mycoplasma hyopneumoniae*. Also, to reduce the incidence of these lesions (as observed in filed studies).
- to reduce viraemia, virus load in lungs and lymphoid tissues and the duration of the viraemic period associated with diseases caused by Porcine circovirus type 2 PCV2. Efficacy against PCV2 genotypes a, b and d has been demonstrated in field studies.
- to reduce culling rate and the loss of daily weight gain caused by *Mycoplasma hyopneumoniae* and/or PCV2 related diseases (as observed at 6 months of age in field studies).

Mycoplasma hyopneumoniae:
Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 23 weeks after vaccination.

Porcine circovirus type 2:
Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 22 weeks after vaccination.

In addition, a reduction in nasal and faecal shedding and the duration of nasal excretion of PCV2 was demonstrated in animals challenged at 4 weeks and at 22 weeks after vaccination.

5. Contraindications

Do not use in case of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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:
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.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.

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:
None known.

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

7. Adverse events

Pigs:

Very common (> 1 animal / 10 animals treated):
Injection site inflammation[1] Depression[2]

Common (1 to 10 animals / 100 animals treated):
Injection site inflammation[3] Elevated temperature[4]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):
Anaphylactic-type reaction (severe allergic reaction)[5]

[1]Mild transient local reactions consisting of non-painful skin inflammations, of less than or equal to 3 cm in diameter.
[2]A slight depression, which subsides in less than 24 hours without treatment is very commonly observed.
[3]Moderate inflammation (between 3-5 cm) at the inoculation site is observed from 4 hours post-vaccination to day three. These local reactions can be observed during the first week after vaccination and last for 1 to 5 days. One or two weeks later, these local reactions can reappear lasting for 1 to 7 days. Local reactions disappear completely within approximately 3 weeks after vaccination without treatment.
[4]Slight transient increase in body temperature (mean 0.6 ºC, in individual pigs less than 2 ºC) that subsides spontaneously within 48 hours without treatment.
[5] Anaphylactic-type reactions (e.g. vomiting, circulatory disorders, dyspnoea) which might be life-threatening, may occur in some sensitive animals. Under these circumstances, appropriate symptomatic treatment should be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For intradermal use.

Administer one dose of 0.2 ml to pigs from 3 weeks of age onwards by intradermal administration at the sides of the neck using a suitable needle-free device able to administer 0.2 ml doses per shot (with an injection stream diameter of 0.25-0.30 mm and a peak force of injection of 0.9-1.3 N).

9. Advice on correct administration

Before use allow the vaccine to reach room temperature.
Shake well before use.

10. Withdrawal periods

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.
Keep the container in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: use immediately.

12. Special precautions for disposal

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. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/20/259/001-004

Pack sizes:
Cardboard box with 1 PET vial of 50 doses (10 ml).
Cardboard box with 1 PET vial of 100 doses (20 ml).
Cardboard box with 1 PET vial of 125 doses (25 ml).
Cardboard box with 1 PET vial of 250 doses (50 ml).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 AMER (Girona) SPAIN
TEL: +34 972 43 06 60

Local representatives and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien
HIPRA BENELUX NV
Nieuwewandeling 62
9000 Gent
BELGIUM
Tel: +32 09 2964464

Република България
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ИСПАНИЯ
Тел: +34 972 43 06 60

Česká republika
HIPRA SLOVENSKO, s.r.o.
Zochova 5,
811 03 Bratislava,
SLOVENSKO
Tel: +421 02 32 335 223

Danmark
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANIEN
Tel: +34 972 43 06 60

Deutschland
HIPRA DEUTSCHLAND GmbH
Am Wehrhahn 28-30
40211 Düsseldorf
DEUTSCHLAND
Tel: +49 211 698236 – 0

Eesti
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
HISPAANIA
Tel: +34 972 43 06 60

Ελλάδα
HIPRA ΕΛΛΑΣ Α.Ε.
Λεωφ. Αθηνών 80 & Μηριόνου 2-4,
104 41 Κολωνός - ΑΘΗΝΑ - ΕΛΛΑΣ
Τηλ: +30 210 4978660

Lietuva
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ISPANIJA
Tel: +34 972 43 06 60

Luxembourg/Luxemburg
HIPRA BENELUX NV
Nieuwewandeling 62
9000 Gent
BELGIUM
Tel: +32 09 2964464

Magyarország
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANYOLORSZÁG
Tel: +34 972 43 06 60

Malta
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANJA
Tel: +34 972 43 06 60

Nederland
HIPRA BENELUX NV
Nieuwewandeling 62
9000 Gent
BELGIUM
Tel: +32 09 2964464

Norge
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANIA
Tlf: +34 972 43 06 60

Österreich
HIPRA DEUTSCHLAND GmbH
Am Wehrhahn 28-30
40211 Düsseldorf
DEUTSCHLAND
Tel: +49 211 698236 – 0

España
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ESPAÑA
Tel: +34 972 43 06 60

France
HIPRA FRANCE
7 rue Roland Garros, Batiment H
44700 - Orvault -
FRANCE
Tél: +33 02 51 80 77 91

Hrvatska
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ŠPANJOLSKA
Tel: +34 972 43 06 60

Ireland
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPAIN
Tel: +34 972 43 06 60

Ísland
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPÁNN
Sími: +34 972 43 06 60

Italia
Hipra Italia S.r.l.
Enrico Mattei, 2
25030 Coccaglio (BS)
ITALIA
Tel: +39 030 7241821

Κύπρος
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ΙΣΠΑΝΙΑ
Τηλ: +34 972 43 06 60

Latvija
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPĀNIJA
Tel. +34 972 43 06 60

Polska
HIPRA POLSKA Sp.z.o.o.
Ul. Wincentego Rzymowskiego 31
02-697 Warszawa - POLSKA
Tel: +48 22 642 33 06

Portugal
ARBUSET, Produtos Farmacêuticos e Sanitários
De Uso Animal, Lda
Portela de Mafra e Fontaínha - Abrunheira
2665 – 191 Malveira - PORTUGAL
Tel:+351 219 663 450

România
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANIA
Tel: +34 972 43 06 60

Slovenija
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ŠPANIJA
Tel: +34 972 43 06 60

Slovenská republika
HIPRA SLOVENSKO, s.r.o.
Zochova 5,
811 03 Bratislava,
SLOVENSKO
Tel: +421 02 32 335 223

Suomi/Finland
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
ESPANJA
Puh/Tel: +34 972 43 06 60

Sverige
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPANIEN
Tel. +34 972 43 06 60

United Kingdom (Northern Ireland)
LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
17170 Amer (Girona)
SPAIN
Tel: +34 972 43 06 60

17. Other information

To stimulate active immunity against *Mycoplasma hyopneumoniae* and Porcine circovirus type 2 in pigs.