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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
White homogeneous emulsion after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

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

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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 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.

4.6 Adverse reactions (frequency and seriousness)

Mild transient local reactions consisting of non-painful skin inflammations, of less than 3 cm in diameter are very common. Moderate inflammation (between 3-5 cm) at the inoculation site is commonly observed from 4 hours post-vaccination to day one. These local reactions can be observed during the first week after vaccination and last for 1 to 4 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.

A slight transient increase in body temperature (mean 0.3 ºC, in individual pigs less than 2 ºC) occurred commonly in field studies. This slight increase subsided spontaneously within 48 hours without treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions
- 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).

4.7 Use during pregnancy, lactation or lay

The use is not recommended during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

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).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated viral and inactivated bacterial vaccines for pigs.
ATCvet code: QI09AL08
To stimulate active immunity against *Mycoplasma hyopneumoniae* and Porcine circovirus type 2 in pigs.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate (EDTA)
Disodium phosphate dodecahydrate
Light mineral oil
Manganese sulfate monohydrate
Poloxamer 407
Polysorbate 80
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Sodium hydroxide
Sorbitan mono-oleate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 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.

6.4. 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.

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 43 06 60 - Fax. +34 972 43 06 61
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/259/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18/09/2020

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 Girona
Spain

Laboratorios Hipra, S.A.
Carretera C-63 km 48.300
Polígono Industrial El Rieral
Amer, 17170 Girona
Spain

Name and address of the manufacturer responsible for batch release

Laboratorios Hipra, S.A.
Avda. la Selva, 135
Amer, 17170 Girona
Spain

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE 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. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intradermal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

10. EXPIRY DATE

EXP {month/year}
Once opened use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/259/001-004

17. MANUFACTURER'S BATCH NUMBER

Batch {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 emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

4. ROUTE(S) OF ADMINISTRATION

Intradermal use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
MHYOSPHERE PCV ID 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 and manufacturer responsible for batch release:
Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 43 06 60 - Fax. +34 972 43 06 61
E-mail: hipra@hipra.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MHYOSPHERE PCV ID emulsion for injection for pigs

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

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

4. INDICATION(S)

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. ADVERSE REACTIONS

Mild transient local reactions consisting of non-painful skin inflammations, of less than 3 cm in diameter are very common. Moderate inflammation (between 3-5 cm) at the inoculation site is commonly observed from 4 hours post-vaccination to day one. These local reactions can be observed during the first week after vaccination and last for 1 to 4 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.

A slight transient increase in body temperature (mean 0.3 ºC, in individual pigs less than 2 ºC) occurred commonly in field studies. This slight increase subsided spontaneously within 48 hours without 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.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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.
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.
Shelf life after first opening the container: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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 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 (symptoms, emergency procedures, antidotes):
None known.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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.

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

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