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 or equal to 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 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.

A slight transient increase in body temperature (mean 0.6 ºC, in individual pigs less than 2 ºC) occurred commonly in field studies. This slight increase subsided spontaneously within 48 hours without treatment.

A slight depression, which subsides in less than 24 hours without treatment is very commonly observed.

Anaphylactic-type reactions (e.g. vomiting, circulatory disorders, dyspnoea) which might be life-threatening, may occur very rarely in some sensitive animals based on post-marketing safety experience. Under these circumstances, appropriate symptomatic treatment should be administered.

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 the HIPRADERMIC device.
Safety and efficacy of MHYOSPHERE PCV ID have been demonstrated using the device HIPRADERMIC.

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 SA
Avda La Selva 135
17170 Amer (Girona)
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 17533/5007

9. DATE OF FIRST AUTHORISATION

18 September 2020

10. DATE OF REVISION OF THE TEXT

July 2023

Approved: 24 July 2023