MHYOSPHERE® PCV ID

Emulsion for injection for pigs

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.
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17170 Amer (Girona)
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Tel. +34 972 43 06 60 - Fax. +34 972 43 06 61
E-mail: hipra@hipra.com

STATEMENT OF THE ACTIVE SUBSTANCE(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.

White homogeneous emulsion after shaking.

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.

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

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 day 1 post-vaccination is commonly observed, which generally decrease to less than 3 cm the next day. These local reactions can be observed during the first week after vaccination and last for 1 to 3 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 1.5 ºC) ocurred 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.

TARGET SPECIES: Pigs.

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).

ADVICE ON CORRECT ADMINISTRATION:

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

WITHDRAWAL PERIOD(S):

Zero days.

SPECIAL STORAGE PRECAUTIONS:

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC – 8 ºC). 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.

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.

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.

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/).

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.

UK: POM-V **IE:** POM Prescription Only Medicine
Local Representative:
HIPRA UK AND IRELAND, Ltd.
Tel: (+44)-(0)11 5845 6486

For Animal Treatment Only

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