# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Persoporc
Lyophilisate and diluent for preparing a suspension for injection, for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

**Active substance:**
Porcine Reproductive Respiratory Syndrome virus (LMY-BP chimera strain)
- at least $10^{3.8}$ $TCID_{50}$

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pig

### 3.2 Indications for use for each target species

For active immunization of pigs from the age of 3-5 weeks against infections with porcine reproductive respiratory syndrome virus (PRRSV) type NA (North America) to reduce mortality, clinical signs including weight loss and lung lesions.

### 3.3 Contraindications

None

### 3.4 Special warnings

Vaccinate healthy animals only.
Do not use in PRRS free herds.
Do not house PRRS free herds with animals vaccinated with Persoporc.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not vaccinate animals with shock or hypersensitivity to this product.
Do not vaccinate animals with fever, malnutrition, infectious disease, or parasitic infection, stressed or immunosuppressed by fungal or bacterial toxin.

Avoid vaccination in stressed animals (change in environment or feed, shipping, etc.). Protect animals from stress 1 week before and after vaccination.

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.

### 3.6 Use during pregnancy, lactation

Do not use in pregnant pigs or boars at mating.

### 3.7 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 depending on veterinarian support.

### 3.8 Administration routes and dosage

For intramuscular or intradermal use.

For preparation of the suspension of injection mix the freeze-dried powder (lyophilsate) with the correspondent amount of the diluent and shake well befor use.

Keep the prepared suspension for injection at room temperature (22-27°C) before use.

Use aseptic syringes and needles.

Sterilise the injection site with 70% alcohol or others to avoid inflammation or pyopoiesis.

Intramuscular administration:

Dissolve the lyophilisate with the sterile diluent and administer 2 ml per piglet intramuscularly around the ear.

Intradermal administration:

Dissolve the lyophilisate with the corresponding amount of sterile diluent and shake well before connecting with the device for intradermal injection.
Administer 0.5 ml per piglet by intradermal route.

Mixing volume of diluent for each administration:

| Presentation | Volume of solvent for i.m. injection | Volume of solvent for Intradermal injection |
|---|---|---|
| 10 doses | 20 mL | 5 mL |
| 50 doses | 100 mL | 25 mL |

### 3.9 Special restrictions for use and special conditions for use

For administration only by a veterinarian.

### 3.10 Withdrawal periods

21 days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code: QI09AD03

This vaccine is designed to stimulate the development of an active immune response to Porcine Reproductive Respiratory Syndrome virus type NA.

## 5. IMMUNOLOGICAL 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
Shelf life after dissolution according to directions: use immediately

### 5.3 Special precautions for storage

Keep out of the reach and sight of children and animals.
Store and transport refrigerated (2°C–8°C).
In order to protect from light, store the vaccine in the original package.
Protect from frost.

### 5.4 Nature and composition of immediate packaging

Freeze-dried vaccine (lyophilizate):
Glass vials of 10 ml (10 doses) or 50 ml (50 doses) with rubber stopper and lacquered aluminium seal.

Diluent:
PP bottles of 20 ml or 100 ml with rubber stopper and aluminium seal.

Not all pack sizes may be marketed.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements.

## 6. NAME AND ADDRESS OF THE MANUFACTURER

BIOPOA Co., Ltd
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18469 KOREA

## 7. MARKETING AUTHORISATION HOLDER

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33500 Libourne, France