1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:
Actinobacillus pleuropneumoniae antigen concentrate containing:

OMP [outer membrane protein]	50 units*
Apx I toxoid	50 units*
Apx II toxoid	50 units*
Apx III toxoid	50 units*

* units relative to an internal standard determined to be efficacious in pigs.

Adjuvant:

dl-α-tocopherol	150 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Formaldehyde (preservative)	0.02 % w/v
Polysorbate 80	
Simethicone	
Sodium chloride	
Water for injections	

Aqueous white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (weaned piglets).

3.2 Indications for use for each target species

For the active immunisation of weaned piglets to reduce mortality, clinical signs and lesions of pleuropneumonia caused by *Actinobacillus pleuropneumoniae.*

Onset of immunity: 2 weeks after completion of the vaccination scheme.
Duration of immunity: 11 weeks after completion of the vaccination scheme.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
It is not advisable to vaccinate animals immediately before and after feeding.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. If spilled on the skin, wash with soap and water.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs (weaned piglets):

Very common (>1 animal / 10 animals treated):	Injection site reaction[1]; Anorexia, Decreased activity, Depression
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[2,3]; Decreased appetite[3] Increased respiratory rate[3,4]; Vomiting[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis

[1] These are mild to moderate reactions, that resolve within 5 days post-vaccination.
[2] Increases up to 2 °C.
[3] Resolve within 24 hours after vaccination.
[4] With a change towards abdominal breathing and dyspnoea.

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:
Do not use during pregnancy or 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

Dose: 2 ml.
Route of administration: Deep intramuscular injection.

Allow the vaccine to reach ambient temperature (between 15 °C to 25 °C) before use.
Shake bottle vigorously before and at intervals during use.
Clean and sterile vaccination equipment should be used.
The use of automatic vaccination equipment is recommended.

Maximum protection should be achieved before the start of the fattening period.
Pigs may be vaccinated from 6 weeks of age.
Two doses at least 4 weeks apart are required. It is advised to give these at 6 and 10 weeks of age.

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

No reactions other than those described in section 3.6 were observed following a double dose; however, the severity of clinical signs was increased.

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: QI09AB07.

The active ingredients (Apx I, Apx II, Apx III and OMP) induce antibodies, which help to protect pigs against pleuropneumonia caused by *Actinobacillus pleuropneumoniae*.
The antigens are incorporated in an aqueous adjuvant in order to enhance stimulation of immunity.

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: 10 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box with one glass bottle type I (Ph. Eur.) or PET bottle with halogenated rubber stoppers and aluminium closures, containing 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).

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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/100/001

8. DATE OF FIRST AUTHORISATION

31/01/2014

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

31/05/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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