Summary of Product Characteristics

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 substance(s):

600 mg *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

Excipient:

Formaldehyde (preservative)	0.02	% w/v

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (weaned piglets).

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Only healthy animals should be vaccinated.

4.5 Special precautions for use

Special precautions for use in animals
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 the 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.

4.6 Adverse reactions (frequency and seriousness)

In laboratory studies and field trials:
Mild to moderate injection site reactions may very commonly occur in some animals, these resolve within 5 days post-vaccination. Anorexia and decreased activity/depression may be very commonly observed after vaccination. Transient increases in temperature (up to 2 °C), lower appetite, vomiting, increases in respiration rate with a change towards abdominal breathing and dyspnea may be commonly observed after vaccination. These reactions are transient and resolve within 24 hours after vaccination.

In post marketing experience:
More severe reactions such as anaphylaxis may very rarely occur.

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).

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy or lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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

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.

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

No reactions other than those described in section 4.6 were observed following a double dose; however, the severity of clinical signs was increased.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae; Inactivated bacterial vaccines; Actinobacillus vaccine.
ATC-vet 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

dl-α-tocopherol acetate
Polysorbate 80
Simethicone
Sodium chloride
Formaldehyde
Water for injection

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: 10 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Carton with one glass bottle type I (Ph. Eur.) or PET bottle with halogenated rubber stoppers and aluminium closures, containing 20, 50, 100 or 250 ml (10, 25, 50 or 125 doses).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet Ireland Limited
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/100/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31 January 2014
Date of last renewal: 31 January 2019

10 DATE OF REVISION OF THE TEXT

March 2019