LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Actinobacillus pleuropneumoniae antigen concentrate containing 50 units OMP [outer membrane protein], 50 units Apx I toxoid, 50 units Apx II toxoid and 50 units Apx III toxoid.

3. PACKAGE SIZE

20 ml (10 doses)
50 ml (25 doses)
100 ml (50 doses)
250 ml (125 doses)

4. TARGET SPECIES

Pigs (weaned piglets)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/3030

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET/GLASS BOTTLE LABEL OF 100 ML AND 250 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Actinobacillus pleuropneumoniae antigen concentrate containing 50 units of each of:
OMP
[outer membrane protein], and Apx I, Apx II and Apx III toxoids.

100 ml
250 ml

3. TARGET SPECIES

Pigs (weaned piglets)

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

Keep the bottle in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PET/GLASS BOTTLE LABEL OF 50 ML AND 20 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 2 ml dose contains:
Actinobacillus pleuropneumoniae antigen concentrate containing 50 units of each of:
OMP
[outer membrane protein], and Apx I, Apx II and Apx III toxoids.

20 ml
50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Porcilis APP suspension for injection for pigs

2. 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

Excipient:

Formaldehyde (preservative)	0.02 % w/v

Aqueous white suspension.

3. Target species

Pigs (weaned piglets).

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

Pregnancy and lactation:
Do not use during pregnancy or 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:
No reactions other than those described in the “Adverse Events” section were observed following a double dose; however, the severity of clinical signs was increased.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. 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 (severe allergic reaction)

[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 (difficulty breathing).

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing

authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

8. Dosage for each species, routes and method of administration

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

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.

9. Advice on correct administration

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.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/3030

Pack sizes:
20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherland

17. Other information

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.

Approved 04 February 2025
Gavin Hall