LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON 20 ml, 50 ml, 100 ml, 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP Suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
600 mg *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.
Also contains 150 mg dl-α-tocopherol (adjuvant) and 0.02% w/v formaldehyde (preservative).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (weaned piglets).

6. INDICATION(S)

[To be included for Member States in which the method of sale and supply of the product is exempt from veterinary prescription:]
For the active immunization of weaned piglets to reduce mortality, clinical signs and lesions of pleuropneumonia caused by *Actinobacillus pleuropneumoniae*.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4606

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 100 ml, 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP Suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
600 mg *Actinobacillus pleuropneumoniae* antigen concentrate containing 50 units of each of: OMP [outer membrane protein], and Apx I, Apx II and Apx III toxoids. Also contains 150 mg dl-α-tocopherol (adjuvant) and 0.02 % w/v formaldehyde (preservative).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml (50 doses)
250 ml (125 doses)

5. TARGET SPECIES

Pigs (weaned piglets).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4606

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 50 ml, 20 ml

Pictogram of a pig

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP Suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 2 ml dose contains:
600 mg *Actinobacillus pleuropneumoniae* antigen concentrate containing 50 units of each of: OMP [outer membrane protein], and Apx I, Apx II and Apx III toxoids. Also contains dl-α-tocopherol and formaldehyde.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml (10 doses)
50 ml (25 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}
Once opened use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Porcilis APP Suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis APP Suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 2 ml dose contains 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	
dl-α-tocopherol (adjuvant)	150 mg	
Formaldehyde (preservative)		0.02 % w/v

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

4. INDICATION(S)

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. ADVERSE REACTIONS

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).

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.

7. TARGET SPECIES

Pigs (weaned piglets).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD(S)

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'.

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

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 (symptoms, emergency procedures, antidotes):
No reactions other than those described in the “Adverse Reactions” section were observed following a double dose; however, the severity of clinical signs was increased.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

Pack sizes: 20, 50, 100 or 250 ml (10, 25, 50 or 125 doses).
Not all pack sizes may be marketed.

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.

Approved 14 August 2020