[Version 9,10/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suigen APP 2,9,11 emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (1 ml) of the vaccine contains:

Active substances:

Inactivated strains of:	
Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11**	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

* RP = Relative potency (determined by ELISA method) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test on the target species.
** The serovars 9 and 11 are determined together as one value because the potency test is not able to distinguish between these 2 antigen variants.

Adjuvant:

Montanide ISA 35 VG	0.2 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Sodium chloride	
Water for injection	

The ready to use vaccine has a milky liquid of light grey to white colour and may contain a small amount of sediment which easily disperses after shaking.

3. CLINICAL INFORMATION

3.1 Target species

Pig

3.2 Indications for use for each target species

For active immunisation of pigs from 6 weeks of age onwards to reduce lung lesions and to reduce colonisation of the respiratory tract caused by pleuropneumonia due to *Actinobacillus pleuropneumoniae* serovars expressing the APX toxins I, II and III.

Onset of immunity: 3 weeks after the second dose
Duration of immunity: 20 weeks after the second dose

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:

Not applicable

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very common (>1 animal / 10 animals treated):	- Injection site induration
Common (1 to 10 animals / 100 animals treated):	- Injection site swelling* - Injection site reddening - Elevated temperature**

* with a diameter of 10 cm which spontaneously subsides within 3 to 14 days
** up to 0.8°C for 1 or 2 days after injection

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

The safety of the veterinary medicinal product has not been established during pregnancy and 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

Before use, allow the vaccine to reach room temperature of 15 to 25 °C and shake well.
Administer intramuscularly (preferably to the paraauricular area) one dose (1ml) of the veterinary medicinal product according to the following regimen of vaccination.

From an age of 6 weeks, administer 2 doses at an interval of 3 weeks

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

No other adverse reactions were observed after an overdose administration (2 doses) of the veterinary medicinal product other than those described in section 3.6, except for a temporary elevation of body temperature up to 1.5 °C in some of the animals.

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

Immunological properties
The vaccine contains inactivated whole-cell antigens of *Actinobacillus pleuropneumoniae* s.2, s.9 and s.11 and toxoids APX I, APX II and APX III. The vaccination with these antigens induce an active immunisation to protect against the consequences of field infection by *Actinobacillus pleuropneumoniae*.

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.

5.4 Nature and composition of immediate packaging

High density polyethylene vial of 15, 60, 120 or 250 ml volume, glass vial (hydrolytic glass class I) of 10 ml or glass vial (hydrolytic glass class II) of 50 and 100 ml sealed with a chlorobutyl rubber stopper for perforation and an aluminium cap or flip-off cap , in a cardboard or plastic box with 10 wells.
Package Leaflet is a part of each packaging.

Package sizes:

Cardboard box:
1 x 10 ml (1 x 10 doses) in 10 ml glass vial hydrolytic class I,
1 x 10 ml (1 x 10 doses) in 15 ml HDPE plastic vial,
10 x 10 ml (10 x 10 doses) in 10 ml glass vial hydrolytic class I,
1 x 50 ml (1 x 50 doses) in 50 ml glass vial hydrolytic class II,
1 x 50 ml (1 x 50 doses) in 60 ml HDPE plastic vial,
1 x 100 ml (1 x 100 doses) in 100 ml glass vial hydrolytic class II,
1 x 100 ml (1 x 100 doses) in 120 ml HDPE plastic vial,
1 x 250 ml (1 x 250 doses) in 250 ml HDPE plastic vial

Plastic box:
10 x 10 ml (10 x 10 doses) in 10 ml glass vial hydrolytic class I

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

Medicines should not be disposed of via wastewater or household waste.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

DD/MM/YYYY

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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

ANNEX II

Not applicable

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX
PLASTIC BOX WITH COVER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suigen APP 2,9,11 emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each vaccination dose (1 ml) contains:
Active substances:
Inactivated strains of:

Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11**	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

* RP = Relative potency (determined by ELISA method) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.
** The serovars 9 and 11 are determined together as one value because the potency test is not able to distinguish between these 2 antigen variants.

3. PACKAGE SIZE

10 ml
50 ml,
100 ml,
250 ml
10×10 ml

4. TARGET SPECIES

Pig

5. INDICATIONS

For active immunisation of pigs from 6 weeks of age onwards to reduce lung lesions and to reduce colonisation of the respiratory tract caused by pleuropneumonia due to *Actinobacillus pleuropneumoniae* serovars expressing the APX toxins I, II and III.

Onset of immunity: 3 weeks after the second dose
Duration of immunity: 20 weeks after the second dose

6. ROUTES OF ADMINISTRATION

Intramuscular route

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 (2 °C – 8 °C).
Do not freeze.

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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PAPER ETIQUETTE 100 ml (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suigen APP 2,9,11 emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each vaccination dose (1 ml) contains:
Active substances:
Inactivated strains of:

Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11**	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

* RP = Relative potency (determined by ELISA method) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.
** The serovars 9 and 11 are determined together as one value.

3. TARGET SPECIES

Pig

4. ROUTES OF ADMINISTRATION

Intramuscular route.
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 (2 °C – 8 °C).
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PAPER ETIQUETTE 10 ml (50ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suigen APP 2,9,11 emulsion for injection for pigs

2. QUALITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated strains of:
Actinobacillus pleuropneumoniae serovar 2
Actinobacillus pleuropneumoniae serovar 9
Actinobacillus pleuropneumoniae serovar 11
toxoid APX I
toxoid APX II
toxoid APX III

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

Suigen APP 2,9,11 emulsion for injection for pigs

2. Composition

Each vaccination dose (1 ml) contains:

Active substances:

Inactivated strains of:	
Actinobacillus pleuropneumoniae serovar 2	RP ≥ 1*
Actinobacillus pleuropneumoniae serovars 9, 11**	RP ≥ 1*
toxoid APX I	RP ≥ 1*
toxoid APX II	RP ≥ 1*
toxoid APX III	RP ≥ 1*

* RP = Relative potency (determined by ELISA method) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target species.
** The serovars 9 and 11 are determined together as one value because the potency test is not able to distinguish between these 2 antigen variants.

Adjuvant:

Montanide ISA 35 VG	0.2 ml

Excipients:

Thiomersal	0.1 mg
Sodium chloride	
Water for injection	

The ready to use vaccine has a milky liquid of light grey to white colour and may contain a small amount of sediment which easily disperses after shaking.

3. Target species

Pig

4. Indications for use

For active immunisation of pigs from 6 weeks of age onwards to reduce lung lesions and to reduce colonisation of the respiratory tract caused by pleuropneumonia due to *Actinobacillus pleuropneumoniae* serovars expressing the APX toxins I, II and III.

Onset of immunity: 3 weeks after the second dose
Duration of immunity: 20 weeks after the second dose

5. Contraindications

None

6. Special warnings

Special warnings:
Vaccinate healthy animals only

Special precautions for safe use in the target species:

Not applicable

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Interactions 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 other adverse reactions were observed after an overdose administration (2 doses) of the veterinary medicinal product other than those described in section “Adverse events”, except for a temporary elevation of body temperature up to 1.5 °C in some of the animals.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

Do not mix with any other veterinary medicinal product

7. Adverse events

Very common (>1 animal / 10 animals treated):	- Injection site induration
Common (1 to 10 animals / 100 animals treated):	- Injection site swelling* - Injection site reddening. - Elevated temperature**

* with a diameter of 10 cm which spontaneously subside within 3 to 14 days.
** up to 0.8°C for 1 or 2 days after injection

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.

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

Vaccination: Piglets from the age of 6 weeks are vaccinated with 2 doses of 1.0 ml, 3 weeks apart.
Administration route: Intramuscular, preferably to the paraauricular area.

9. Advice on correct administration

Before use, allow the vaccine to reach room temperature of 15 to 25 °C and shake well.

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.

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

Shelf life after first opening the container: 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers

Cardboard box:
1 x 10 ml (1 x 10 doses) in 10 ml glass vial hydrolytic class I,
1 x 10 ml (1 x 10 doses) in 15 ml HDPE plastic vial,
10 x 10 ml (10 x 10 doses) in 10 ml glass vial hydrolytic class I,
1 x 50 ml (1 x 50 doses) in 50 ml glass vial hydrolytic class II,
1 x 50 ml (1 x 50 doses) in 60 ml HDPE plastic vial,
1 x 100 ml (1 x 100 doses) in 100 ml glass vial hydrolytic class II,
1 x 100 ml (1 x 100 doses) in 120 ml HDPE plastic vial,
1 x 250 ml (1 x 250 doses) in 250 ml HDPE plastic vial

Plastic box:
10 x 10 ml (10 x 10 doses) in 10 ml glass vial hydrolytic class I

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder:
VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros Cedex
France
Telephone: +33 492 08 73 04

Manufacturer responsible for batch release:
Bioveta a.s.
Komenského 212/12
683 23 Ivanovice na Hané
Czechia
Telephone: 00420 517 318 500

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.