Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Suivac APP emulsion for injection for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 2 ml contains:

Active substances:

Inactivated *Actinobacillus pleuropneumoniae,* serotype 2, strain *App2TR98*		1.0 - 10.0 U*
Inactivated *Actinobacillus pleuropneumoniae,* serotype 9, strain *App9KL97*		1.0 - 10.0 U*
expressing APXI toxoid	(from App 9)	1.0 - 10.0 U*
expressing APXII toxoid	(from App 2 and 9)	1.0 - 10.0 U*
expressing APXIII toxoid	(from App 2)	1.0 - 10.0 U*

*One unit (1 U) corresponds to the total titrated amount of antibodies detected with ELISA in serum from vaccinated mice.

Adjuvants:
Emulsigen 0.36 ml,
Saponin (extract from Quillaja Saponaria Molina) 0.10 mg.

Excipients:
Thiomersal 0.10 mg.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Emulsion for injection for pigs.
White or yellowish-white liquid.
By leaving to stand still an easily suspended sediment may be formed.

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs (piglets, sows and gilts)

4.2 Indications for use, specifying the target species

Active immunisation of pigs from six weeks of age for the reduction of mortality, clinical symptoms and lung lesions caused by *Actinobacillus pleuropneumoniae* serotypes 2 and 9 infections.

Onset of immunity: 3 weeks after the primary vaccination.

Duration of immunity: 22 weeks following second vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

No information is available on the efficacy of the vaccine in animals with maternally derived antibodies.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.

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.

4.6 Adverse reactions (frequency and seriousness)

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

Adverse reactions to the vaccine include:

Piglets and fattening pigs
- Vomiting is very common on the day of vaccination
- Inappetence is very common on the day of vaccination and for up to 3 days after vaccination
- Somnolence is very common on the day of vaccination and for up to 3 days after vaccination
- Slight oedema is very common on the day after vaccination
- body temperature commonly increases by up to 1.8 °C for 4 - 6 hours on the day of vaccination

Some of these symptoms are pathognomonic of anaphylactic type reaction of mid severity.

Breeding stock (sows and gilts)
- Vomiting is very common on the day of vaccination
- Inappetence is very common on the day of vaccination and for 1 day after vaccination
- Somnolence is very common on the day of vaccination
- Slight oedema is very common on the day of vaccination and for 1 day after vaccination
- body temperature commonly increases by up to 1.6 °C for 4 hours on the day of vaccination

No treatment is necessary in case of above mentioned adverse reactions.
Symptomatic treatment has to be applied in case of an anaphylactic reaction.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy. The use is not recommended later than 2 weeks before expected farrowing.

Lactation:
Use is not recommended during 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

The vaccine dose is 2 ml per animal per vaccination regardless of age, sex and body weight. Primary vaccination consists of administration of 2 doses, 3 - 4 weeks apart, by deep intramuscular injection in the neck behind the ear.

Animals should be vaccinated from 6 weeks of age.

The primary vaccination of pregnant sows and gilts should take place at 8 and 4 weeks before expected farrowing.

Revaccination: A single revaccination is carried out 3 to 4 weeks before the expected date of farrowing and is intended to boost antibody titres in pregnant sows and gilts. This revaccination schedule has been demonstrated to be safe, however the antibody titre increase has not been investigated.

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

Administration of a double dose caused no reactions other than those described in section 4.6 (adverse reactions).

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccine - Actinobacillus/haemophilus vaccine.
ATCvet code: QI09AB07.

5.1 Pharmacodynamic properties

The vaccine contains inactivated *Actinobacillus pleuropneumoniae* bacteria. Strain *App2TR98* belongs to the serotype 2 expressing APXIII whereas strain *App9KL97* belong to the serotype 9 expressing APXI. Both strains also express APXII. Vaccinated animals develop specific antibodies against *Actinobacillus pleuropneumoniae* serotype 2 and serotype 9. Those antibodies are transferred to the off-spring through colostrum.
After primary immunisation of piglets in field trials, antibodies were detected up to an age of 143 days. Raised antibody titres are maintained for up to 3 months after completion of the two dose vaccination course.

Suivac APP is an inactivated purified subunit toxoid vaccine against *Actinobacillus*. The vaccine is intended for active immunisation of piglets from 6 weeks of age.

A certain degree of cross-immunisation with a reduction in lung lesions was documented for serotypes 1, 3, 5, 6, 7 and 11 after challenge in 6 - 10 weeks old piglets.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsigen
Saponin
Thiomersal
Sodium chloride

Water for injections

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

50 ml (25 doses) in a HDPE plastic vial, closed with a siliconised rubber stopper and an aluminium cap. Placed in a cardboard box.

100 ml (50 doses) in a HDPE plastic vial, closed with a siliconised rubber stopper and an aluminium cap. Placed in a cardboard box.

500 ml (250 doses) in a HDPE plastic vial, closed with a siliconised rubber stopper and an aluminium cap. Placed in a cardboard box.

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

ChemVet dk A/S
A.C. Illums Vej 6
Silkeborg
8600
Denmark

8 MARKETING AUTHORISATION NUMBER(S)

VPA10395/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 October 2016
Date of last renewal: 29 May 2020

10 DATE OF REVISION OF THE TEXT

June 2020