[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyobac App 2 Vet., emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	**Per dose (1.0 ml)**
Actinobacillus pleuropneumoniae, serotype 2, strain WLSB 3012	RP ≥ 1* max. 4.2 x 10^{10} CFU min. 4.2 x 10^{09} CFU
APX II toxoid strain WSLB 3012	RP ≥ 1* max. 2.5 µg min. 0.25 µg
APX III toxoid strain WSLB 3012	RP ≥ 1* max. 2.3 µg min. 0.23 µg

* Relative potency (RP) is determined by comparison with reference preparation conforming to challenge test on target animals according to requirements of Ph. Eur. monograph, as amended.

Adjuvant:
Emulsigen (mineral oil) 0.2 ml

Excipients:

Thiomersal	0.1 mg
Sodium chloride	max. 9 mg
Water for injection	ad 1 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

Opaque white emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For active immunization of pigs to protect against clinical symptoms and to reduce lung lesions caused by an infection with *Actinobacillus pleuropneumoniae* serotype 2.

Onset of immunity: 3 weeks after revaccination.

Duration of immunity: min. 20 weeks after revaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Temper the vial content to a room temperature (+15°C to +25°C) and shake well before use.

Special precautions for use in animals
Only clinically healthy animals should be vaccinated.

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)
In vaccinated animals, very commonly a transient average rise in temperature of 1.4°C and commonly a transient rise in temperature up to 2.8°C is observed. The temperature decreases to the normal range within the first two days following vaccination.
Very rarely, a large proportion of animals may react in some specific herds after vaccination with immediate anaphylactic-type reactions, resulting in clinical signs such as hyperthermia, dyspnea, recumbency, lethargy, muscle shaking, erythema and vomiting. The animals normally recover within 30 minutes, while recovery from reduced activity normally occurs within 12 hours.
In case of severe anaphylactic reactions, which may be lethal, appropriate treatment is recommended.

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

4.8 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 other veterinary medicinal products. 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
Vaccination programme:
1 dose (1 ml) is injected deeply into the neck musculature behind the ear from 6 weeks of age.

Revaccination with one dose 2-3 weeks later.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
A double dose of vaccine very often results in an increase in temperature of 0,7ºC on average and often to an increase of up to 1.2ºC. The temperature normalizes within the first 3 days following

vaccination. Tenderness and transient swelling on the injection site occur very often and disappear gradually within the first 3 days following vaccination. Tremor and/or somnolence occur very often and disappear spontaneously within the first 6 hours following vaccination. Vomiting occur very often if piglets are vaccinated after feeding.

4.11 Withdrawal period(s)
Zero days.

5. IMMUNOLOGICAL PROPERTIES
Pharmacotherapeutic group: Inactivated bacterial vaccine (actinobacillus/haemophilus) for pigs.
ATC vet code: QI09AB07.

The vaccine contains inactivated *Actinobacillus pleuropneumoniae* s. 2 antigen and Apx II and Apx III toxoids that are gradually absorbed from the injection site. Following parenteral administration, these antigens induce production of specific antibodies that help to protect the vaccinated animal against clinical symptoms and to reduce lung lesions caused by a field *A. pleuropneumoniae* infection.

In vaccinated pigs a significant reduction of clinical symptoms of *Actinobacillus pleuropneumoniae* was observed after challenge infection.

5.1 Pharmacodynamic properties
None.

5.2 Environmental properties
None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Emulsigen (mineral oil) 20%
Thiomersal
Sodium chloride
Water for injection

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

6.3 Shelf life
2 years
Shelf-life after first opening the immediate packaging – 10 hours.

Shelf life of the veterinary medicinal product as packaged for sale:
Shelf life after first opening the immediate packaging:

6.4. Special precautions for storage
Store in a refrigerator (2 °C to 8 °C).
Do not freeze.
Store in the original container.

6.5 Nature and composition of immediate packaging
High-density polyethylene (HDPE) vials: 120 ml vial containing 100 ml.
Type II glass vials: 100 ml vial containing 100 ml.
Both HDPE and glass vials have pierceable chlorobutyl rubber stoppers and aluminium caps.
Outer package of paper cardboard.

Package size:
1 x 100 ml.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Salfarm Danmark A/S
Fabriksvej 21, 6000 Kolding
Denmark
Tel: +45 75529413
E-mail: sal@salfarm.com

8. MARKETING AUTHORISATION NUMBER(S)

48942

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: April 10th, 2012
Date of last renewal: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

December 12th, 2016

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyobac App 2 Vet., emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances

	Per dose (1.0 ml)
Actinobacillus pleuropneumoniae, serotype 2, strain WSLB 3012	RP ≥ 1* max. 4.2 x 10^{10} CFU min. 4.2 x 10^{09} CFU
APX II toxoid strain WSLB 3012	RP ≥ 1* max. 2.5 µg min. 0.25 µg
APX III toxoid strain WSLB 3012	RP ≥ 1* max. 2.3 µg min. 0.23 µg

* Relative potency (RP) is determined by comparison with reference preparation conforming to challenge test on target animals according to requirements of Ph. Eur. monograph, as amended.

Adjuvant
Emulsigen (mineral oil) 0.2 ml

Excipients
Thiomersal
Sodium chloride
Water for injection

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

1 x 100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

For active immunization of pigs for protection against clinical symptoms and to reduce lung lesions caused by an infection with *Actinobacillus pleuropneumoniae serotype 2.*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Injected deeply intramuscularly behind the base of the ear from the age of 6 weeks.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: 0 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 (2 °C to 8 °C).
Do not freeze.
Store in the original container.

12. SPECIAL 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

Salfarm Danmark A/S
Fabriksvej 21, 6000 Kolding
Denmark
Tel: +45 75529413
E-mail: sal@salfarm.com

16. MARKETING AUTHORISATION NUMBER(S)

DK: 48942
SE: 55369

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyobac App 2 Vet., emulsion for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substances

	Per dose (1.0 ml)
Actinobacillus pleuropneumoniae, serotype 2, strain WSLB 3012	RP ≥ 1* max. 4.2 x 10^{10} CFU min. 4.2 x 10^{09} CFU
APX II toxoid strain WSLB 3012	RP ≥ 1* max. 2.5 µg min. 0.25 µg
APX III toxoid strain WSLB 3012	RP ≥ 1* max. 2.3 µg min. 0.23 µg

* Relative potency (RP) is determined by comparison with reference preparation conforming to challenge test on target animals according to requirements of Ph. Eur. monograph, as amended.

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

100 ml.

4. ROUTE(S) OF ADMINISTRATION

Injected deeply intramuscularly behind the ear.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: 0 days.

6. BATCH NUMBER

Lot:

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:
Hyobac App 2 Vet., emulsion for injection

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

Marketing authorisation holder
Salfarm Danmark A/S, Fabriksvej 21, 6000 Kolding, Denmark. Tel: +45 75529413, E-mail: sal@salfarm.com

Manufacturer responsible for batch release:
Bioveta, a.s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyobac App 2 Vet., emulsion for injection

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

Active substances:

	Per dose (1.0 ml)
Actinobacillus pleuropneumoniae, serotype 2, strain WSLB 3012	RP ≥ 1* max. 4.2 x 10^{10} CFU min. 4.2 x 10^{09} CFU
APX II toxoid strain WSLB 3012	RP ≥ 1* max. 2.5 µg min. 0.25 µg
APX III toxoid strain WSLB 3012	RP ≥ 1* max. 2.3 µg min. 0.23 µg

* Relative potency (RP) is determined by comparison with reference preparation conforming to challenge test on target animals according to requirements of Ph. Eur. monograph, as amended.

Adjuvant:

Emulsigen (mineral oil)	0.2 ml

Excipients:

Thiomersal	0.1 mg
Sodium chloride	max. 9 mg
Water for injection	ad 1 ml

Opaque, white emulsion.

4. INDICATION(S)

For active immunization of pigs for protection against clinical symptoms and to reduce lung lesions caused by an infection with *Actinobacillus pleuropneumoniae serotype 2.*
The active immunity onset is apparent in the vaccinated pigs 21 days after revaccination and it lasts for at least of 20 weeks.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In vaccinated animals, very commonly a transient average rise in temperature of 1.4°C and commonly a transient rise in temperature up to 2.8°C is observed. The temperature decreases to the normal range

within the first two days following vaccination. Very rarely, a large proportion of animals may react in some specific herds after vaccination with immediate hypersensitivity-type reactions, resulting in clinical signs such as fever, encumbered breathing, lying down, dullness, muscle shaking, redness and vomiting. The animals normally recover within 30 minutes, while recovery from reduced activity normally occurs within 12 hours.
In case of severe hypersensitivity reactions, which may be lethal, appropriate treatment is recommended.

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).

7. TARGET SPECIES
Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION
Vaccination programme:
1 dose (1 ml) is injected deeply into the neck musculature behind the ear from 6 weeks of age.

Revaccination with the same dose 2-3 weeks later.

9. ADVICE ON CORRECT ADMINISTRATION
Allow the vaccine to reach room temperature (15°C to 25°C) before use. Shake before use.

10. WITHDRAWAL PERIOD(S)
Slaughter: 0 days.

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.

Store in a refrigerator (2°C to 8°C).
Do not freeze.
Store in the original container.

Do not use this veterinary medicinal product after the expiry date which is stated on the label
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)
Special precautions for use in animals:
Only clinically healthy animals should be vaccinated.

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.

Overdose (symptoms, emergency procedures, antidotes):
A double dose of vaccine very often results in an increase in temperature of 0,7°C on average and often to an increase of up to 1.2°C. The temperature normalizes within the first 3 days following vaccination. Tenderness and transient swelling on the injection site occur very often and disappear gradually within the first 3 days following vaccination. Tremor and/or somnolence occur very often and disappear spontaneously within the first 6 hours following vaccination. Vomiting occur very often if piglets are vaccinated after feeding.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 12th, 2016