SUMMARY OF PRODUCT CHARACTERISTICS

Hyobac App Multi Vet., emulsion for injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyobac App Multi Vet., emulsion for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	Per dose (1.0 ml)
Actinobacillus pleuropneumoniae, serotype 2, strain WSLB 3012	RP ≥ 1* min. 1,4 x 10^{09} CFU max. 1.4 x 10^{10} CFU
Actinobacillus pleuropneumoniae, serotype 5, strain WSLB 3079 / serotype 6, strain WSLB 3075	RP ≥ 1* min. 1.4 x 10^{09} CFU for each strain max. 1.4 x 10^{10} CFU for each strain
Toxoid APX I	RP ≥ 1* min. 0.228 µg max. 2.28 µg
Toxoid APX II	RP ≥ 1* min. 0.290 µg max. 2.90 µg
Toxoid APX III	RP ≥ 1* min. 0.125 µg max. 1.25 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 the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

Milky liquid of light grey to white colour.
A small amount of sediment may appear, which disperses after shaking.

4. CLINICAL PARTICULARS

4.1 Target species

Pig.

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, 5, and 6.

The active immunity onset is apparent in the vaccinated pigs 21 days after revaccination and it lasts for at least 20 weeks.

4.3 Contraindications

None.

4.4 Special warning

None.

4.5 Special precautions for use

Temper the vial content to room temperature (15°C to 25°C) and shake 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 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 product, seek prompt medical advice even if only a very small amount is injected and bring the patient information leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This 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 an involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Slight apathy, somnolence and tremor occur very commonly following application and will disappear spontaneously within a few hours. Vomiting is very commonly observed in pigs vaccinated immediately after being fed. Local reactions (redness and/or swelling) very commonly appear at the injection site. This reaction disappears within several days spontaneously. Temporary elevations of body temperatures of up to 1.1°C can occur in vaccinated animals.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions 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).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or 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 possible decision regarding use of the vaccine immediately before or after another veterinary medicinal product must therefore 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 the same dose 3 weeks later.

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

Double dose of the vaccine causes no side effects in the target animals, except from the adverse reactions mentioned under 4.6 Adverse reactions.

4.11 Withdrawal periods

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccine (actinobacillus/haemophilus) for pigs.
ATCvet-code: QI 09AB07

The vaccine contains inactivated *Actinobacillus pleuropneumoniae* s. 2, s. 5 and s. 6 antigens and APX I, 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 infection with *A. pleuropneumoniae*. Pleuropneumonia caused by other serotypes of *A. pleuropneumoniae* that produces APX I, II, and III toxoids is reduced by vaccination.
In vaccinated pigs a significant reduction of clinical symptoms of *Actinobacillus pleuropneumoniae* was observed after challenge infection.

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.

6.4 Special precautions for storage
Store in a refrigerator (2^{o}C to 8^{o}C).
Store in original container.
Do not freeze.

6.5 Nature and composition of immediate packaging
High density polyethylene (HDPE) vials: 250 ml vial containing 250 ml or 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, 1 x 250 ml

Not all pack sizes may be marketed.

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
DK - 6000 Kolding

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

July 11th, 2014

10. DATE OF REVISION OF THE TEXT