SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS Salm emulsion for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vaccine dose (1 ml) contains:
Active substances:
Inactivated strains of:

Salmonella enterica subsp. *enterica* sv. Typhimurium	RP ≥ 1*
Salmonella enterica subsp. *enterica* sv. Derby	RP ≥ 1*
Salmonella enterica subsp. *enterica* sv. Infantis	RP ≥ 1*

*****) Relative potency (RP) is determined by comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test in the target animals.

Adjuvant:

Montanide ISA 206 VG	0.54 ml

Excipients:

Formaldehyde	max. 0.50 mg/ml
Thiomersal	0.1 mg/ml

For the 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 (pregnant gilts and sows)

4.2 Indications for use, specifying the target species

For the passive immunisation of piglets by the active immunisation of pregnant gilts and sows in order to induce colostral antibodies against strains of *Salmonella enterica* subsp. *enterica* serovar Derby, *S. enterica* subsp. *enterica* serovar Infantis and *S. enterica* subsp. *enterica* serovar Typhimurium. In suckling piglets passive immunisation leads to a decrease in colonisation of inner organs (ileo-caecal lymph nodes, ileal wall and colon wall) by the above *Salmonella* serovars.

Onset of immunity: passive protection commences from the start of colostrum intake
Duration of immunity: in naturally suckled piglets protection will persist for 30 days (in piglets weaned at 21 days of age)

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only. Passive protection of piglets depends on adequate ingestion of colostrum as soon as possible after birth.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

Application site reactions in the form of erythema occurred commonly in field studies and persist mostly 2 to 4 days. A transient increase in rectal temperature (mean increase not greater than of 0.7 °C but may be up to 1.2 °C in individual animals) may commonly occur in the first 24 hours after injection.

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

Pregnancy and lactation:

Can be used during pregnancy.

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 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

Intramuscular use.
Vaccination dose: 1.0 ml
Allow the vaccine to reach room temperature (+15 °C to +25 °C) before use.
Shake well before use. The vaccine is an opaque, white emulsion with visible sediment which is evenly dispersed after shaking.
Use only sterile equipment, e.g. syringes and needles.

Administer the vaccine by deep intramuscular injection behind the ear. The site of injection should be clean, dry and aseptically treated.

Primary vaccination:
The primary vaccination consists of two doses and is administered from 10 months of age: The first dose is administered 4 weeks before the expected parturition and the second dose 2 weeks later.
Revaccination:
In subsequent gestation periods administer one dose of the vaccine 2 weeks before each expected parturition. The efficacy of the revaccination scheme has not been investigated by challenge of piglets, but by the evaluation of antibody levels in vaccinated gilts after the booster dose.

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

Not applicable.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for suidae, inactivated bacterial vaccines, *Salmonella*
ATC vet code: QI09AB14

The vaccine contains inactivated cells of selected serovars of *Salmonella enterica* subsp. *enterica*. Colostral antibodies from vaccinated mothers was shown to be effective for progeny at 30 days of age against the mentioned pathogens when piglets are suckled up to 21 days of age. In laboratory challenge studies, bacterial colonisation of ileum and colon of piglets by the *Salmonella* serovars included in the vaccine was reduced.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde
Montanide ISA 206 VG
Thiomersal
Potassium dihydrogen phosphate
Di-Sodium hydrogen phosphate dodecahydrate
Sodium chloride

Water for injection

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 and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Store in the original container.
Protect from light.

6.5 Nature and composition of immediate packaging

The vaccine is supplied in High-density polyethylene (HDPE) vials or type I glass vials with pierceable chlorobutyl rubber stoppers and aluminum caps or flip-off caps. The packing 1 x 10 ml, 1 x 50 ml and 1 x 100 ml are supplied in carton box. The packing 10 x 10 ml is supplied in plastic box with ten holes. The approved package insert is enclosed.

a) single package
1 x 10 ml – glass vial
1 x 50 ml, 1 x 100 ml – polyethylene vial (volumes 60 ml and 120 ml)

b) multi package
10 x 10 ml – glass vial

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

Bioveta, a.s.
Komenského 212/12
Ivanovice na Hané
683 23
Czech Republic

8. MARKETING AUTHORISATION NUMBER

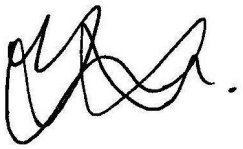
Vm 46608/4000

9. DATE OF FIRST AUTHORISATION

07 December 2020

10. DATE OF REVISION OF THE TEXT

December 2020



Approved: 07 December 2020