A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box
1 x 10 ml – glass vial,
1 x 50 ml, 1 x 100 ml – plastic vial (60 ml, 120 ml)
Plastic box
10 x 10 ml – glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS Salm emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances (1 ml):
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.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

1 x 10 ml, 1 x 50 ml, 1 x 100 ml, 10 x 10 ml

5. TARGET SPECIES

Pigs (pregnant gilts and sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Allow the vaccine to reach room temperature (+15 °C to +25 °C) before use.
Shake well before use.

10. EXPIRY DATE

EXP: {month/year}
After first opening use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Store in the original container.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 46608/4000

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

glass vial 10 ml, plastic vial 60 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS Salm emulsion for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substances (1 ml):
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

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

10 doses (10 ml), 50 doses (50 ml)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP: {month/year}
After first opening use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

plastic vial 120 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS Salm emulsion for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances (1 ml):
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.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

100 doses (100 ml)

5. TARGET SPECIES

Pigs (pregnant gilts and sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Allow the vaccine to reach room temperature (+15 °C to +25 °C) before use.
Shake well before use.

10. EXPIRY DATE

EXP: {month/year}
After first opening use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Store in the original container.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 46608/4000

17. MANUFACTURER'S BATCH NUMBER

Batch:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
BIOSUIS Salm emulsion for injection for pigs

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

Marketing authorisation holder and manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS Salm emulsion for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

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

Opaque, white emulsion.

4. INDICATION(S)

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)

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs (pregnant gilts and sows)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.
Vaccination dose: 1.0 ml
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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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 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.

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.

Pregnancy: Can be used during pregnancy.

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.

Incompatibilities: Do not mix with any other veterinary medicinal product.

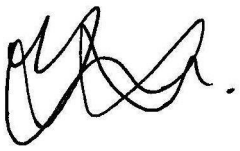
13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.
Not all pack sizes may be marketed.



Approved: 07 December 2020