

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
(CZ, AT, DE, EE, EL, FR, HU, IE, IT, PL, SK)
Smartvac Salmonella emulsion for injection for pigs
(BE, NL)

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances (1 ml):

Inactivated strains of:

Salmonella enterica subsp. *enterica* sv. Typhimurium RP \geq 1*

Salmonella enterica subsp. *enterica* sv. Derby RP \geq 1*

Salmonella enterica subsp. *enterica* sv. Infantis RP \geq 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)

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
(CZ, AT, DE, EE, EL, FR, HU, IE, IT, PL, SK)
Smartvac Salmonella emulsion for injection for pigs
(BE, NL)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substances (1 ml):

Inactivated strains of:

<i>Salmonella enterica</i> subsp. <i>enterica</i> sv. Typhimurium	RP ≥ 1
<i>Salmonella enterica</i> subsp. <i>enterica</i> sv. Derby	RP ≥ 1
<i>Salmonella enterica</i> subsp. <i>enterica</i> 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
(CZ, AT, DE, EE, EL, FR, HU, IE, IT, PL, SK)
Smartvac Salmonella emulsion for injection for pigs
(BE, NL)

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances (1 ml):

Inactivated strains of:

<i>Salmonella enterica</i> subsp. <i>enterica</i> sv. Typhimurium	RP \geq 1*
<i>Salmonella enterica</i> subsp. <i>enterica</i> sv. Derby	RP \geq 1*
<i>Salmonella enterica</i> subsp. <i>enterica</i> sv. Infantis	RP \geq 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”

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