A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

cardboard box / 1 × 10 ml, 1 × 50 ml, 1 × 100 ml, 1 × 250 ml
label for plastic box / 10 × 10 ml
label for glass vial / 100 ml
label for plastic vial / 120 ml (filled volume 100 ml), **250 ml**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS ParvoEry suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Composition 2 ml (1 dose):

Porcine parvovirus, inactivated, strain CAPM V198, S-27	≥ 4 $\log_2$ *)
Erysipelothrix rhusiopathiae inactivated, serotype 2, strain 2-64	RP ≥ 1 **)

*), **) see package leaflet

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

1 × 10 ml (5 doses), 1 × 50 ml (25 doses), 1 × 100 ml (50 doses), 1 × 250 ml (125 doses)
10 × 10 ml (5 doses)
100 ml (50 doses)
250 ml (125 doses)

5. TARGET SPECIES

Pigs (gilts, sows)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP
Once opened use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from frost.
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)

UK(NI): Vm 46608/3000
POM-V

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

label for glass vial / 10 ml, 50 ml
label for plastic vial / 60 ml (filled volume 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS ParvoEry suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Composition 2 ml (1 dose):

Porcine parvovirus, inactivated, strain CAPM V198, S-27	≥ 4 $\log_2$
Erysipelothrix rhusiopathiae inactivated, serotype 2, strain 2-64	RP ≥ 1

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

10 ml (5 doses), 50 ml (25 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:
Once opened use within 10 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

POM
POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

BIOSUIS ParvoEry suspension 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 ParvoEry suspension for injection for pigs

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

Each dose (2 ml) contains:
Active substances:
Porcine parvovirus, inactivated, strain CAPM V198, S-27 ≥ 4 $\log_2$ *)
Erysipelothrix rhusiopathiae inactivated, serotype 2, strain 2-64 RP ≥ 1 **)

*) titer HI antibodies in guinea-pig serum after application of ¼ dose for pigs. Antibodies titer 16 and more must be proved in 4 from 5 guinea-pigs. The resulting value of HI titre is given by mean of titres of antibodies reached in 5 guinea pigs.
**) Relative potency (RP) is given by comparison of antibody level in serum of vaccinated mice with antibody level in mice serum prepared with reference vaccine batch, which complies in challenge test on target animals according to the Phr. Eur. requirements

Adjuvants:
Aluminium hydroxide ***) 9.0 mg
***) Hydrated, for adsorption 2% (expressed as Al_2O_3)

Excipients: Formaldehyde max. 1.0 mg
Thiomersal 0.2 mg

Suspension for injection.
Milky white up to greyish-white liquid. During longer standing the content separates into a clear liquid and milky white to greyish sediment.

4. INDICATION(S)

For active immunisation of pigs (gilts, sows) to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae* and to prevent transplacental infection of embryos and foetuses of gilts and sows caused by porcine parvovirus.

Onset of immunity:
Porcine parvovirus: 3 weeks after primary vaccination (from the beginning of pregnancy)
E. rhusiopathiae: 3 weeks after primary vaccination

Duration of immunity:
Porcine parvovirus: for the duration of pregnancy
E. rhusiopathiae: 6 months

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient slight increase in body temperature (maximum 0.9 °C) lasting at the most for 4 days after vaccination has been observed very commonly in studies.
Redness at the injection site lasting up to 4 days after vaccination occurred commonly in the laboratory safety studies.
Swelling at the injection site (maximum 3 cm diameter), persisting up to 6 days after vaccination occurred commonly in the laboratory safety studies.
The vaccination could induce very rare the hypersensitivity reaction in animals sensitive to erysipelas infection.

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.

7. TARGET SPECIES

Pigs (gilts, sows).

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

One dose: 2 ml
Route of administration: intramuscular, into the neck muscles behind the ear.

Gilts
Primary vaccination – from 6 months of age: administer 2 doses approximately 6 weeks and 3 weeks before insemination. In case of previous vaccination against both porcine parvovirus and erysipelas with monovalent vaccines produced by Bioveta, a.s. (where authorised, 1 dose against erysipelas administered from 8 weeks of age and 1 dose

against porcine parvovirus administered 6 weeks before insemination), one dose of the combined vaccine 3 weeks before insemination is sufficient.
Regular revaccination with one dose may be given at least 3 weeks before each insemination (but not later than 6 months after previous vaccination).

Sows
Primary vaccination - in case of previous vaccination against both porcine parvovirus and erysipelas with vaccines produced by Bioveta, a.s. (where authorised, see administration schedule for gilts), one dose of combined vaccine 3 weeks before insemination is sufficient.
If the sows were not previously vaccinated as gilts (before first farrowing), primary vaccination schedule described for gilts should be followed.
Regular revaccination with one dose may be given at least 3 weeks before each insemination (but not later than 6 months after previous vaccination).

9. ADVICE ON CORRECT ADMINISTRATION

The vaccine is recommended temperate before application to the room temperature and shake the content gently before and occasionally during application (in 250 ml packaging before and also during application, in other packaging after longer standing). Use sterile injection material without antiseptic and/or disinfected compounds.
Keep general conditions of asepsis.
Do not use BIOSUIS ParvoEry suspension for injection if you notice a visible signs of destroying of primary packaging material.

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).
Protect from frost.
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.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy: Do not use during pregnancy.

Lactation: Can be used during lactation.

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

Overdose (symptoms, emergency procedures, antidotes), if necessary: not applicable.

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.

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

August 2021

15. OTHER INFORMATION

Packaging:
Cardboard box: 1 × 10 ml (5 doses in 10 ml glass vials)
1 × 50 ml (25 doses in 50 ml glass vials or 60 ml plastic vials)
1 × 100 ml (50 doses in 100 ml glass vials or 120 ml plastic vials)
1 × 250 ml (125 doses in a 250 ml plastic vials)
Plastic box: 10 × 10 ml (10 × 5 doses in 10 ml glass vials)
Not all pack sizes may be marketed.

Marketing authorisation number:
UK(NI): Vm 46608/3000
POM-V

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 04/11/21