1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BIOSUIS ParvoEry suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:

Porcine parvovirus, strain CAPM V198, S-27, inactivated $\geq 4 \log_2$ *)

Erysipelothrix rhusiopathiae, serotype 2, strain 2-64, inactivated RP ≥ 1 **)

*) Titre HI antibodies in guinea-pig serum after application of ¼ dose for pigs. Antibodies titre 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 Ph. Eur. requirements.

Adjuvants:

Aluminium hydroxide ***) 9.0 mg

***) Hydrated, for adsorption 2% (expressed as Al_2O_3)

Excipients:Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
Formaldehyde	
Sodium chloride	
Water for injections	

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs (gilts, sows).

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs (gilts, sows):

Very common (>1 animal / 10 animals treated):	Elevated temperature [1]
Common (1 to 10 animals / 100 animals treated):	Injection site reddening [2] Injection site swelling [3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction [4]

[1] - maximum 0.9 °C, lasting up to 4 days after vaccination.
[2] - lasting up to 4 days after vaccination.
[3] - maximum 3 cm diameter, persisting up to 6 days after vaccination.
[4] - in animals sensitive to erysipelas infection.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.

Lactation:
Can be used during lactation.

3.8 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.

3.9 Administration routes and dosage

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

It is recommended that the vaccine is allowed to warm up to the room temperature before application. Shake the contents 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 antiseptics and/or disinfect.
Aseptic conditions should be maintained throughout the vaccination.

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).

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AL01

The vaccine contains inactivated strains of porcine parvovirus and *Erysipelothrix rhusiopathiae* (serotype 2) and stimulates active immunity of pigs against porcine parvovirus and against swine erysipelas (induced by serotypes 1 and 2).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities
Do not mix with any other veterinary medicinal product.

5.2 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

5.3 Special precautions for storage
Store and transport refrigerated (2 °C – 8 °C).
Protect from frost.
Protect from light.

5.4 Nature and composition of immediate packaging
The vaccine is filled to:

glass vials of hydrolytic class I:	10 ml suspension (5 doses) in a 10 ml vial
glass vials of hydrolytic class II:	50 ml suspension (25 doses) in a 50 ml vial
	100 ml suspension (50 doses) in a 100 ml vial
plastic vials:	50 ml suspension (25 doses) in a 60 ml vial
	100 ml suspension (50 doses) in a 120 ml vial
	250 ml suspension (125 doses) in a 250 ml vial

The vials are sealed with chlorobutyl injectable stopper, with aluminium or flip-off caps and placed in a cardboard or plastic box.

The product is delivered in the following pack sizes:
Cardboard box:
1 × 10 ml, 1 × 50 ml, 1 × 100 ml, 1 × 250 ml
Plastic box:
10 × 10 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bioveta, a. s.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22028/003/001

8. DATE OF FIRST AUTHORISATION

03/09/2021

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

22/10/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).