SUMMARY OF PRODUCT CHARACTERISTICS

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (gilts, sows).

4.2 Indications for use, specifying the 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: the vaccination provides the protection of foetuses during the whole pregnancy period.
E. rhusiopathiae: 6 months

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

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
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during pregnancy.

Lactation:
Can be used during lactation.

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

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 vaccination 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).

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 pigs, inactivated viral and inactivated bacterial vaccines
ATC vet 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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide, hydrated, for adsorption
Formaldehyde
Thiomersal
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).
Protect from frost.
Protect from light.

6.5 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 chlorbutyl injectable stopper, with aluminium or flip-off caps and placed in a cardboard or plastic box. The approved package leaflet is attached to each package.

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.

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
683 23 Ivanovice na Hané
Czech Republic

8. MARKETING AUTHORISATION NUMBER

Vm 46608/3000

9. DATE OF FIRST AUTHORISATION

17 May 2021

10. DATE OF REVISION OF THE TEXT

November 2021

Approved: 04/11/21