1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoruvax suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) of vaccine contains:

Active substance:

Inactivated Porcine Parvovirus, K-22 strain ≥ 2 HAI.U

Erysipelothrix rhusiopathiae (lysed bacterial cells), serotype 2 ≥1 Elisa U

1 HAI.U: equivalent to HAI antibody titres of 1 log10 in guinea-pigs after administration of the vaccine.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the pharmaceutical product**
Aluminium-hydroxide	4.2 mg
Thiomersal	0.2 mg
Salt	
Water for injection	

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

For active immunisation of breeding pigs (sows, gilts and boars) against porcine parvovirosis, to reduce the number of stillbirths and mummified piglets, and against erysipelas to reduce or prevent clinical symptoms. The onset of immunity is obtained from 2 to 3 weeks after the primary vaccination. A duration of immunity up to 9 months and 11 months following vaccination has been proven for the parvovirus component and the erysipelas component, respectively.

When mixed with Enteroporc COLI AC:

Duration of immunity after twofold vaccination: up to 2 months for the parvovirus component and up to 4.5 months for the erysipelas component.
Duration of immunity after threefold vaccination: up to 6 months for both parvovirus and erysipelas components.

3.3 Contraindications

None.

3.4 Special warnings

Primary vaccination against porcine parvovirosis should not be carried out in the presence of maternally derived antibodies.
Vaccinate only healthy animals.

3.5 Special precautions for use

Special precautions for use in animals
None

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site reaction [1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[2] Hyperthermia [3]

[1]≤1.5 cm
[2]Especially in animals sensitized by the erysipelas infection. In this case symptomatic treatment such as adrenalin, should be undertaken.
[3] <0.2°C, transient (may last 1 or 2 days after vaccination).

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 section “contact details” of the package leaflet.

3.7 Use during pregnancy, lactation or lay

The vaccine is safe for use during pregnancy and lactation. However, avoid vaccination during the 3 weeks following service mating.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Enteroporc COLI AC and administered at one injection site. The product literature of Enteroporc COLI AC should be consulted before administration. It is important to note that the primary vaccination scheme changes if the vaccines are mixed before administration.
A decision to use this vaccine before or after any other veterinary medicinal product than Enteroporc COLI AC needs to be made on a case-by-case basis.

After the administration of Parvoruvax mixed with Enteroporc COLI AC the following adverse events may occur:

Hyperthermia (mean 1.6 °C, in individual pigs up to 3.3 °C) may occur very commonly on the day of vaccination returning to normal within 24 hours. Injection site swelling may occur very commonly (mean size 1.0 cm, in individual pigs up to 10 cm) disappearing without treatment within 14 days. Injection site reddening and injection site warmth may occur very commonly, disappearing without treatment within 14 days. Slight decreased activity may occur commonly on the day of vaccination. Hyperventilation and pallor may occur uncommonly on the day of vaccination. Hypersensitivity reaction may occur very rarely.

3.9 Administration routes and dosage

Shake well before use.
Apply usual aseptic procedures.
Use sterile and antiseptic- and/or disinfectant-free equipment for injection purposes. Apply usual procedures for the handling of animals.
Inject one 2-ml dose by deep intramuscular injection into the neck muscles behind the ear, to animals of at least 6 months of age.

When Parvoruvax is used alone:

Basic vaccination scheme
2 doses with a 3 to 4-week interval, the second dose being given at least 2 weeks before service mating.

Re-vaccination scheme
1 dose every six months (in females, during the week preceding weaning).

When Parvoruvax is mixed with Enteroporc COLI AC:
Inject one dose (4 ml) of vaccine into neck muscles in the area behind the ear of each pig.

Vaccination scheme:

Primary vaccination:
Three doses:
Two doses with a 3 to 4 week interval. In gilts the first dose is given within 7 weeks before insemination and the second dose being given at least 2 weeks before insemination (e.g., 5 and 2 weeks before insemination).
One dose (third vaccination) is given 2 weeks before the expected date of farrowing.

Revaccination (before each subsequent farrowing):
One dose 2 weeks before the expected date of farrowing.

Preparation of the mixture of Parvoruvax and Enteroporc COLI AC:
1. The whole content of Parvoruvax and Enteroporc COLI AC are combined in an appropriately sized sterile vial using an appropriate transfer system (devices (CE certified) used for mixing should be handled aseptically). The same volumes/ number of doses of Enteroporc COLI AC and Parvoruvax should be used.

2. To ensure appropriate mixing of the vaccines, gently shake the vial containing both vaccines until the mixture is a yellowish brown to reddish brown suspension.

The vaccine mixture is ready to use. Shake well before and occasionally during administration to keep the product homogenous.

Shelf life after mixing according to directions: 8 hours.

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

No undesirable effect except those mentioned in paragraph 3.6 «Adverse reactions» was observed after the administration of a double dose of vaccine.

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
Inactivated adjuvanted vaccine against porcine parvovirosis and swine erysipelas.
The vaccine stimulates active immunity against *Erysipelothrix rhusiopathiae*, shown by challenge carried out with serotypes 1a, 1b and 2.
The vaccine stimulates active immunity against porcine parvovirosis, shown by challenge and by the presence of haemagglutinating inhibiting antibodies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other vaccine/immunological product except with Ceva's Enteroporc COLI AC

5.2 Shelf life

Shelf-life: 24 months.
Use immediately after opening the bottle.

5.3 Special precautions for storage

Store between +2^{O}C and +8^{O}C, protected from light.

5.4 Nature and composition of immediate packaging

Nature of primary packaging elements:
Type I glass bottle
Low density polyethylene (LDPE) bottle
Butyl elastomer closure. Aluminium or aluminium-plastic cap.

Packaging intended for sale:
10 ml (5-dose) bottle, box of 1 bottle.
50 ml (25-dose) bottle, box of 1 bottle.
100 ml (50-dose) bottle, box of 1 bottle.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

VPA10815/052/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 01 May 2002
Date of last renewal: 01 May 2007

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

21/05/2026

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*).