Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PARVORUVAX

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2-ml dose of vaccine contains:

Inactivated Porcine Parvovirus, K-22 strain	≥ 2	HAI.U
Erysipelothrix rhusiopathiae(lysed bacterial cells), serotype 2	≥1	Elisa U
Aluminium hydroxide (expressed in Al^{+++})	4.2	mg
Thiomersal	0.2	mg

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Gilts, sows and boars.

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

4.5 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.

4.6 Adverse reactions (frequency and seriousness)

Vaccination can occasionally cause reactions of hypersensitivity in some animals, particularly in those animals sensitised by the erysipelas infection. In such case, appropriate treatment such as adrenaline should be provided.
Rarely, vaccination can induce a small local reaction (<1.5cm) at the site of injection without any effect on the health or productivity of the animal.The vaccination can cause a slight rise in body temperature (<0.2°C) that returns to normal values from 1 to 2 days after vaccination without any consequence to the health or productivity of the animal.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

No information is available on the safety and efficacy on the concurrent use of PARVORUVAX with any other vaccine. It is therefore recommended that no other vaccine be administered within 14 days before or after vaccination with PARVORUVAX.

4.9 Amounts to be administered and administration route

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.

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).

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No undesirable effect except those mentioned in paragraph 4.6 «Adverse reactions» was observed after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Inactivated adjuvanted vaccine against porcine parvovirosis and swine erysipelas.

ATC Vet Code: QI09AL01

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium Hydroxide
Thiomersal
Salt
Water for injection

6.2 Major incompatibilities

Do not mix with any other vaccine/immunological product.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store between +2°C and +8°C, protected from light.

6.5 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)

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/052/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10 DATE OF REVISION OF THE TEXT

September 2020