

## **1 NAME OF THE VETERINARY MEDICINAL PRODUCT**

PARVOVAX.

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 2-ml dose of vaccine contains:

Inactivated porcine parvovirus, minimum	2.0 HAI.U
Thiomersal, maximum	0.2 mg
Oily adjuvant which includes light paraffin oil	449.6 to 488.2mg
Benzyl alcohol	10.56mg

1 HAI.U: q.s. to obtain HAI antibody titres of 1 log<sub>10</sub> in guinea-pigs after administration of the vaccine.

For a full list of excipients see section 6.1.

## **3 PHARMACEUTICAL FORM**

Emulsion for injection.

## **4 CLINICAL PARTICULARS**

### **4.1 Target Species**

Breeder pigs.

### **4.2 Indications for use, specifying the target species**

For active immunisation of breeder pigs (gilts, sows, boars) against porcine parvovirus, to reduce the number of stillbirths and mummified foetuses in vaccinates. The onset of immunity is obtained from 2 to 3 weeks after the primary vaccination. This immunity persists for up to one year.

### **4.3 Contraindications**

None.

### **4.4 Special warnings for each target species**

Vaccinate only healthy animals. Vaccinate sows during lactation.

## **4.5 Special precautions for use**

### **Special precautions for use in animals**

None.

### **Special precautions to be taken by the person administering the medicinal product to animals**

Apply usual aseptic procedures.

#### To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

#### To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

## **4.6 Adverse reactions (frequency and seriousness)**

Vaccination can induce a very small ( $\leq 0.5$ cm) local reaction (granuloma) at the site of injection that disappears about one week later. Rarely vaccination may induce a slight rise in body temperature (around 1°C) that returns to normal within 1-2 days. These effects are without consequence to the health or reproductive performance of the animal.

## **4.7 Use during pregnancy, lactation or lay**

Can be used during pregnancy and lactation.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

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

#### **4.9 Amounts to be administered and administration route**

Apply usual procedures for the handling of animals.

It is recommended to vaccinate all the breeders when implementing the vaccination programme.

Shake well before use.

Inject one 2-ml dose by deep intramuscular injection into the neck muscles behind the ear, according to the following schedule:

##### **Basic Vaccination scheme**

###### -Sows

One dose only during lactation and at the latest on weaning day.

###### - Gilts and young boars over 6 months of age

In the absence of porcine parvovirus antibodies:

1 dose two weeks before service mating.

In the presence of maternally derived antibodies to porcine parvovirus or where the status is unknown as regards maternally derived antibodies:

2 doses with a 15- or 21-day interval, the second dose being given at least 10 days before service mating.

##### **Re-vaccination Scheme**

###### -Sows:

Annual 2 ml dose preferably during lactation and prior to weaning;

###### - Boars

Annual 2 ml dose.

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

No undesirable effect (other than that described in Section 4.6) was observed after the administration of a double dose of vaccine.

#### **4.11 Withdrawal period(s)**

Zero days.

## **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

ATC Vet code: QI09AA02

Inactivated vaccine in adjuvant against porcine parvovirus.

The vaccine stimulates active immunity against porcine parvovirus, shown by challenge or by the presence of haemagglutination inhibiting antibodies.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Benzyl Alcohol

Ether of fatty alcohols and of polyols

Light paraffin oil

Polyoxyethylene fatty acids

Salts

Thiomersal

Trolamine Water for Injection

### **6.2 Major incompatibilities**

Do not mix with any other medicinal product.

### **6.3 Shelf-life**

Shelf-life: 24 months.

Use immediately after opening.

### **6.4 Special precautions for storage**

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

### **6.5 Nature and composition of immediate packaging**

Type 1 glass bottle; Nitrile elastomer closure; Aluminium cap;

1-dose bottle, 1-bottle package.

1-dose bottle, 10-bottle package.

5-dose bottle, 1-bottle package.

25-dose bottle, 1-bottle package.

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)**

VPA10815/053/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 6<sup>th</sup> November 2002

Date of last renewal: 6<sup>th</sup> November 2007

## **10 DATE OF REVISION OF THE TEXT**

November 2017