SUMMARY OF PRODUCT CHARACTERISITICS

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 488.2 mg
Benzyl alcohol……	10.56mg

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

For 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 Contra-indications

None.

4.4 Special warnings for each target species

Vaccinate only healthy animals. Vaccinate sows during lactation.

4.5 Special precautions for use

(i) Special precautions for use in animals

None.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to the 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 (<0.5cm) 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 1oC) 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

<u>Sows:</u>
One dose only during lactation and at the latest on weaning day.

<u>Gilts and young boars over 6 months of age:</u>
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 periods

Zero days.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Inactivated vaccine in adjuvant against porcine parvovirosis.

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

ATC Vet Code:

QI09AA02

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

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 product.

6.3 Shelf-life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time

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

6.4 Special precautions for storage

Store and transport between +2oC and +8oC, 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 product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

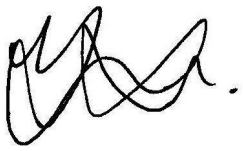
Vm 15052/4149

9. DATE OF FIRST AUTHORISATION

17 October 2005

10. DATE OF REVISION OF THE TEXT

October 2022



Approved: 06 October 2022