[Version 8.1, 01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoruvax suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose 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.

Excipient:

Aluminium hydroxide (expressed in Al^{+++})	4.2 mg
Thiomersal	0.2 mg

For the 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.

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

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 interaction

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. 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^{O}C and +8^{O}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 product 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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 x 5 doses, 1 x 25 doses, 1 x 50 doses package

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoruvax suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated Porcine Parvovirus, K-22 strain	≥ 2 HAI.U
Erysipelothrix rhusiopathiae (lysed bacterial cells), serotype 2	≥1 Elisa U

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

1 x 5 doses (10 ml)
1 x 25 doses (50 ml)
1 x 50 doses (100 ml)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use and disposal.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after opening the bottle.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name
Address
Country}

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 doses, 25 doses, 50 doses bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoruvax suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Porcine parvovirus min. 2.0 HAI.U

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses
25 doses
50 doses

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Parvoruvax suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Manufacturer responsible for batch release:

Ceva-Phylaxia Co. Ltd.
1107 Budapest, Szállás u. 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Parvoruvax suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 2 ml dose 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.

Excipient:

Aluminium hydroxide (expressed in Al^{+++})	4.2 mg
Thiomersal	0.2 mg

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Gilts, sows and boars.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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).

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store between +2^{O}C and +8^{O}C, protected from light.
Use immediately after opening the bottle.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

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.

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.

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

Interaction with other medicinal products and other forms of interaction:
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.

Overdose (symptoms, emergency procedures, antidotes):
No undesirable effect except those mentioned in paragraph 4.6 «Adverse reactions» was observed after the administration of a double dose of vaccine.

Incompatibilities:
Do not mix with any other vaccine/immunological product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MM/YYYY

15. OTHER INFORMATION

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.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.