SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PARVO Vet., suspension for injection
DK, SE : Porcilis Parvo Vet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (2 ml) contains:

Active substance

Inactivated Porcine Parvovirus strain 014	≥ 552 EU*

Adjuvant

dl-α-tocopherol acetate	150 mg

Excipient

Formaldehyde	1.08 mg

* as determined in the final product by antigenic mass ELISA

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection
Nearly white liquid

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

For protection against contagious foetal death in pigs caused by infection with Porcine Parvovirus (PPV).

4.3 Contraindications

None known.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals
Not applicable

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 or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

After vaccination a slight rise in temperature, some reluctance to move and a transient local swelling (<5 cm) at the site of injection may be seen. In very rare cases, a hypersensitivity reaction may occur.

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 and efficacy from the concurrent use of this vaccine with any other except a vaccine from Intervet containing inactivated Erysipelas antigen. It is therefore recommended that no other vaccines should be administered within 14 days before or after administration of the product.

4.9 Amounts to be administered and administration route

Allow the vaccine to reach room temperature (15-25°C) before vaccination. Shake well before and during use.
Dose per pig is 2 ml, to be given by deep intramuscular injection behind the ear.
Basic vaccination: Gilts: One vaccination between 8 and 2 weeks before the first mating.
Sows: One vaccination at least 2 weeks before mating.
Revaccination: Once a year.

Due to possible interference with maternally derived antibodies gilts should not be vaccinated before 6 months of age.

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

No adverse effects other than the ones mentioned under 4.6 have been reported after administration of a double dose.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI 09 AA 02. Pharmacotherapeutic group: Porcine Parvovirus vaccine.
By vaccination of sows and gilts with Porcine Parvovirus (PPV strain 014) active immunisation is achieved and the embryos and foetuses are protected against infection. Protective immunity is reached when vaccination takes place 2-4 weeks prior to service and protection is efficient for one year (i.e. the following two pregnancy periods). The antigens are incorporated in a tocopherol based emulsion acting as adjuvant.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Formaldehyde, Polysorbate 80, Simethicone, Sodium chloride, Water for injections

6.2 Incompatibilities

Do not mix with any other vaccine or immunological product.

6.3 Shelf life

2 years
After first opening: 10 hours at 15-25°C.

6.4 Special precautions for storage

Store at 2-8°C. Do not freeze.

6.5 Nature and composition of immediate packaging

20, 50 or 100 ml PET-bottles (polyethylene terephthalate: PET) or vials of type I (Ph.Eur.) glass are filled with respectively 10, 25 or 50 doses and are closed with a nitryl rubber stopper (Ph.Eur.) and sealed with a coded aluminium cap.
Box with 1 bottle of 10 (20ml), 25 (50ml) or 50 doses (100ml) and box with 10 bottles of 10 doses (20 ml)

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 materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
NL-5831 AN Boxmeer

Name and address of local representative

8. MARKETING AUTHORISATION NUMBER(S)

National license number: Denmark 14729

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

DK: 20-12-2001

10. DATE OF REVISION OF THE TEXT

October 2015

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Parvo, suspension for injection
DK, SE: Porcilis Parvo Vet

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 2 ml:

Inactivated PPV:	≥ 552 EU (antigenic mass ELISA)
dl-α-tocopherol acetate:	150 mg, Formaldehyde

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

1 bottle of 10 (20 ml), 25 (50 ml) or 50 doses (100 ml) or 10 x 10 doses (20 ml)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Vaccine against contagious foetal death in pigs caused by infection with Porcine Parvovirus (PPV).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous – see package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours

11. SPECIAL STORAGE CONDITIONS

Store at 2°-8°C. Do not freeze.

12. 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

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

Keep out of the reach and sight of children

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
NL – 5831 AN Boxmeer

15. MARKETING AUTHORISATION NUMBER(S)

16. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Parvo, suspension for injection
DK, SE: Porcilis Parvo Vet.

2. QUANTITY OF THE ACTIVE SUBSTANCE

Per dose: ≥ 552 EU inactivated PPV (antigenic mass ELISA)

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

10 (20 ml), 25 (50 ml) or 50 doses (100 ml)

4. ROUTE OF ADMINISTRATION

i.m.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Lot: {batch number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use within 10 hours

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGING LEAFLET

PACKAGE LEAFLET

PORCILIS PARVO

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

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
NL – 5831 AN Boxmeer
The Netherlands

As represented by the local company

Manufacturer for the batch release:
Intervet International B.V.
Wim de Körverstraat 35
NL – 5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Parvo, suspension for injection
Denmark, Sweden: Porcilis Parvo Vet.

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

Per dose of 2 ml:
Inactivated Porcine Parvovirus strain 014: ≥ 552EU as determined in the final product by antigenic mass ELISA
adjuvant: dl-α-tocopherol acetate: 150 mg
preservative: Formaldehyde

Nearly white liquid.

4. INDICATION

For protection against contagious foetal death in pigs caused by infection with Porcine Parvovirus (PPV).

5. CONTRAINDICATIONS

None known

6. ADVERSE REACTIONS

After vaccination a slight rise in temperature, some reluctance to move and a transient local swelling (<5 cm) at the site of injection may be seen. In very rare cases, a hypersensitivity reaction may occur.

7. TARGET SPECIES

Pigs

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

The dose is 2 ml.
Deep intramuscular injection behind the ear.

9. ADVICE ON CORRECT ADMINISTRATION

Basic vaccination
Gilts: one vaccination between 8 and 2 weeks before the first mating.
Sows: one vaccination at least 2 weeks before mating.
Because of possible interference with maternally derived antibodies gilts should not be vaccinated before 6 months of age.

Revaccination
Once a year

Allow the vaccine to reach room temperature (15-25°C) before vaccination. Shake well before and during use.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store at 2-8°C. Do not freeze.

12. SPECIAL WARNING(S)

In the case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other except a vaccine from Intervet containing inactivated Erysipelas antigen. It is

therefore recommended that no other vaccines should be administered within 14 days before or after administration of the product.

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

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

14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

October 2015

15. OTHER INFORMATION

By vaccination of sows and gilts with Porcine Parvovirus (PPV strain 014) active immunisation is achieved and the embryos and foetuses are protected against infection. Protective immunity is reached when vaccination takes place 2-4 weeks prior to service and protection is efficient for one year (i.e. the following two pregnancy periods).The antigens are incorporated in a tocopherol based emulsion acting as adjuvant.

Pack-sizes: 10 (20 ml), 25 (50 ml) or 50 doses (100 ml).

Not all pack-sizes may be marketed.