SPC

Porcilis® Ery+ Parvo+Lepto

SUMMARY OF PRODUCT CHARACTERISTICS

July 2016

MSD Animal Health

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 2 ml contains:

Active substances:
Inactivated strains of:
- *Erysipelothrix rhusiopathiae*, serotype 2 (strain M2) ≥ 1 ppd[1]
- Porcine parvovirus (strain 014) ≥ 130 U[2]
- *Leptospira interrogans* serogroup Canicola serovar Portland-Vere (strain Ca-12-000) ≥ 2816 U[2]
- *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001) ≥ 210 U[2]
- *Leptospira interrogans* serogroup Australis serovar Bratislava (strain As-05-073) ≥ 1704 U[2]
- *Leptospira kirschneri* serogroup Grippotyphosa serovar Dadas (strain Gr-01-005) ≥ 648 U[2]
- *Leptospira interrogans* serogroup Pomona serovar Pomona (strain Po-01-000) ≥ 166 U[2]
- *Leptospira santarosai* serogroup Tarassovi serovar Gatuni (strain S1148/02) ≥ 276 U[2]

Adjuvant:
dl-α-tocopheryl acetate 150 mg

Excipient:
Formaldehyde (preservative) 0.4-1 mg
[1] Pig protective dose as compared to a reference preparation known to be protective in pigs.
[2] As determined in the *in vitro* antigenic mass ELISA potency test.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Homogenous white to nearly white suspension after shaking.

4. CLINICAL PARTICULARS

4.1 Target species
Pig for reproduction.

4.2 Indications for use, specifying the target species

For the active immunization of pigs:
- to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2.
- to reduce transplacental infection, viral load and foetal mortality caused by Porcine parvovirus.
- to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), infection and bacterial excretion caused by *L. interrogans* serogroup Canicola serovar Canicola.
- to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), severity of infection and foetal mortality caused by *L. interrogans* serogroup Pomona serovar Pomona.
- to reduce infection caused by *L. interrogans* serogroup Icterohaemorrhagiae serovars Copenhageni and Icterohaemorrhagiae, *L. interrogans* serogroup Australis serovar Bratislava, *L. kirschneri* serogroup Grippotyphosa serovars Grippotyphosa and Bananal/Liangguang, *L. weilii* serogroup Tarassovi serovar Vughia and *L. borgpetersenii* serogroup Tarassovi serovar Tarassovi.

Onset of Immunity:
E. rhusiopathiae: 3 weeks
Porcine parvovirus: 10 weeks
Leptospira serogroups: 2 weeks

Duration of Immunity:
E. rhusiopathiae: 6 months
Porcine parvovirus: 12 months
Leptospira serogroup Australis: 6 months
Leptospira serogroups Canicola, Icterohaemorrhagiae, Grippotyphosa, Pomona and Tarassovi: 12 months

4.3 Contraindications
None.

4.4 Special warnings for each target species
None.

4.5 Special precautions for use

Special precautions for use in animals
Vaccinate only healthy animals.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)
Transient local reactions, mostly consisting of red, mild to hard, non-painful swellings are a very common observation. In general, local reactions may have a diameter of ≤ 5 cm, in very rare cases local reactions in individual animals can be up to 20 cm in diameter. All local reactions disappear completely within approximately 2 weeks after vaccination. In individual animals intermediate systemic reactions, such as vomiting, redness, rapid breathing and twitching, may rarely be observed, which resolve in a few minutes. In individual animals transient reductions in feed intake or activity may uncommonly occur. Feed intake and activity are completely restored within a week. An increase in body temperature may very commonly occur up until two days after vaccination. The observed mean increase was 0.5°C (in individual cases the maximum increase was 1.5°C).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route
Before use allow the vaccine to reach room temperature.
Shake well before use.
Avoid introduction of contamination.

For intramuscular use.
Administer a single dose of 2 ml in the neck region.

Basic vaccination scheme: Pigs which have not yet been vaccinated shall be given a primary injection 6 to 8 weeks before the expected date of insemination and a booster injection 4 weeks later.

Revaccination: A single revaccination with the veterinary medicinal product should be given once a year. Six months post each vaccination with the veterinary medicinal product, a single revaccination with an *Erysipelotrix rhusiopathiae* containing product should be given to maintain immunity against *Erysipelotrix rhusiopathiae*. In case of known infection pressure with *L. interrogans* serogroup Australis, a single revaccination with the veterinary medicinal product should be given every six months, as it is unknown if or for how long the duration of immunity for this serogroup persists beyond six months.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)
Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae. Inactivated viral and inactivated bacterial vaccine for pigs. ATC vet code: QI09AL07.

The product stimulates the development of active immunity in pigs against *E. rhusiopathiae*, Porcine parvovirus, *L. interrogans* serogroup Canicola serovar Canicola, *L. interrogans* serogroup Icterohaemorrhagiae serovars Copenhageni and Icterohaemorrhagiae, *L. interrogans* serogroup Australis serovar Bratislava, *L. kirschneri* serogroup Grippotyphosa serovars Grippotyphosa and Bananal/Liangguang, *L. interrogans* serogroup Pomona serovar Pomona, *L. weilii* serogroup Tarassovi serovar Vughia and *L. borgpetersenii* serogroup Tarassovi serovar Tarassovi.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Formaldehyde
dl-α-tocopheryl acetate
Polysorbate 80
Simethicone
Sodium chloride
Potassium Chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Water for injection

6.2 Incompatibilities
Do not mix with any other veterinary medicinal product.

6.3 Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage
Store in a refrigerator (2°C–8°C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging
PET vials of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses) are closed with a halogenobutyl rubber stopper (type I, Ph. Eur.) and sealed with an aluminium cap.

Pack size:
Cardboard box with 1 vial of 20 ml.
Cardboard box with 10 vials of 20 ml.
Cardboard box with 1 vial of 50 ml.
Cardboard box with 10 vials of 50 ml.
Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 250 ml.

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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V., as represented by the national company
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated *Erysipelothrix rhusiopathiae*, Porcine parvovirus and *Leptospira*

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

20 ml (10 doses)
10x 20 ml (10 doses)
50 ml (25 doses)
10x 50 ml (25 doses)
100 ml (50 doses)
250 ml (125 doses)

5. TARGET SPECIES

Pig for reproduction

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use in the neck.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
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

Intervet International B.V.
5831 AN Boxmeer
The Netherlands
As represented by the national companies in the member states.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
PET vials (20 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated *Erysipelothrix rhusiopathiae,* Porcine parvovirus and *Leptospira*

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

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

i.m.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

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

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS
PET vials (50, 100 and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated Erysipelothrix rhusiopathiae, Porcine parvovirus and Leptospira

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml (25 doses)
100 ml (50 doses)
250 ml (125 doses)

5. TARGET SPECIES

Pig for reproduction

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS
PET vials (50, 100 and 250 ml)

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light

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

Disposal: read the 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

Intervet International B.V.
5831 AN Boxmeer
The Netherlands
As represented by the national companies in the member states.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

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

Marketing authorisation holder:
The national representative of
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

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

Each dose of 2 ml contains:

Active substances:
Inactivated strains of:
- *Erysipelothrix rhusiopathiae*, serotype 2 (strain M2) ≥ 1 ppd[1]
- Porcine parvovirus (strain 014) ≥ 130 U[2]
- *Leptospira interrogans* serogroup Canicola serovar Portland-Vere (strain Ca-12-000) ≥ 2816 U[2]
- *Leptospira interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni (strain Ic-02-001) ≥ 210 U[2]
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- *Leptospira kirschneri* serogroup Grippotyphosa serovar Dadas (strain Gr-01-005) ≥ 648 U[2]
- *Leptospira interrogans* serogroup Pomona serovar Pomona (strain Po-01-000) ≥ 166 U[2]
- *Leptospira santarosai* serogroup Tarassovi serovar Gatuni (strain S1148/02) ≥ 276 U[2]

Adjuvant:

dl-α-tocopheryl acetate 150 mg

Excipient:

Formaldehyde (preservative) 0.4-1 mg

[1] Pig protective dose as compared to a reference preparation known to be protective in pigs.
[2] As determined in the *in vitro* antigenic mass ELISA potency test.

4. INDICATION(S)

For the active immunization of pigs:
- to reduce clinical signs (skin lesions and fever) of swine erysipelas caused by *Erysipelothrix rhusiopathiae*, serotype 1 and serotype 2
- to reduce transplacental infection, viral load and foetal mortality caused by Porcine parvovirus.
- to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), infection and bacterial excretion caused by *L. interrogans* serogroup Canicola serovar Canicola
- to reduce clinical signs (increase of body temperature and reduction in feed intake or activity), severity of infection and foetal mortality caused by *L. interrogans* serogroup Pomona serovar Pomona.
- to reduce infection caused by *L. interrogans* serogroup Icterohaemorrhagiae serovars Copenhageni and Icterohaemorrhagiae, *L. interrogans* serogroup Australis serovar Bratislava, *L. kirschneri* serogroup Grippotyphosa serovars Grippotyphosa and Bananal/Liangguang, *L. weilii* serogroup Tarassovi serovar Vughia and *L. borgpetersenii* serogroup Tarassovi serovar Tarassovi

Onset of Immunity:
E. rhusiopathiae: 3 weeks
Porcine parvovirus: 10 weeks
Leptospira serogroups: 2 weeks

Duration of Immunity:
E. rhusiopathiae: 6 months
Porcine parvovirus: 12 months
Leptospira serogroup Australis: 6 months
Leptospira serogroups Canicola, Icterohaemorrhagiae, Grippotyphosa, Pomona and Tarassovi: 12 months

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Transient local reactions, mostly consisting of red, mild to hard, non-painful swellings are a very common observation. In general, local reactions may have a diameter of ≤ 5 cm, in very rare cases local reactions in individual animals can be up to 20 cm in diameter. All local reactions disappear completely within approximately 2 weeks after vaccination. In individual animals intermediate systemic reactions, such as vomiting, redness, rapid breathing and twitching, may rarely be observed, which resolve in a few minutes. In individual animals transient reductions in feed intake or activity may uncommonly occur. Feed intake and activity are completely restored within a week. An increase in body temperature may very commonly occur up until two days after vaccination. The observed mean increase was 0.5°C (in individual cases the maximum increase was 1.5°C).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pig for reproduction

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

For intramuscular use. Administer a single dose of 2 ml in the neck region.

Basic vaccination scheme: Pigs which have not yet been vaccinated shall be given a primary injection 6 to 8 weeks before the expected date of insemination and a booster injection 4 weeks later.

Revaccination: A single revaccination with the veterinary medicinal product should be given once a year. Six months post each vaccination with the veterinary medicinal product, a single revaccination with an *Erysipelotrix rhusiopathiae* containing product should be given to maintain immunity against *Erysipelotrix rhusiopathiae*. In case of known infection pressure with *L. interrogans* serogroup Australis, a single revaccination with the veterinary medicinal product should be given every six months, as it is unknown if or for how long the duration of immunity for this serogroup persists beyond six months.

9. ADVICE ON CORRECT ADMINISTRATION

Before use allow the vaccine to reach room temperature.
Shake well before use.
Avoid introduction of contamination.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2°C–8°C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for target species:
None.

Special precautions for use in animals:
Vaccinate only healthy animals.

Special precautions to be taken by the person administrating the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package insert or label to the physician.

Use during pregnancy, lactation or lay:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interactions:
No information is available on the safety and efficacy of this vaccine with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions other than those mentioned in section 6 were observed after the administration of a double dose of vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

Pack size:
Cardboard box with 1 vial of 20 ml.
Cardboard box with 10 vials of 20 ml.
Cardboard box with 1 vial of 50 ml.
Cardboard box with 10 vials of 50 ml.
Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 250 ml.

Not all pack sizes may be marketed.