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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. 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)

4. TARGET SPECIES

Pigs for reproduction

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

EXP {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS: “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3016

15. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated *Erysipelothrix rhusiopathiae*, Porcine parvovirus and *Leptospira*
20 ml (10 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}
Once broached use within 10 hours.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

PET vials (50, 100 and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo+Lepto suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Inactivated *Erysipelothrix rhusiopathiae*, Porcine parvovirus and *Leptospira*
50 ml (25 doses)
100 ml (50 doses)
250 ml (125 doses)

3. TARGET SPECIES

Pigs for reproduction

4. ROUTES OF ADMINISTRATION

Intramuscular use. Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

6. EXPIRY DATE

EXP {mm/yyyy}
Once broached use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Porcilis Ery+Parvo+Lepto suspension for injection for pigs

2. Composition

Each 2 ml dose 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)	≥ 1310 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

[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.

Homogenous white to nearly white suspension after shaking.

3. Target species

Pigs for reproduction.

4. Indications for use

For the active immunisation 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 fetal 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: 1 year
Leptospira serogroup Australis: 6 months
Leptospira serogroups Canicola, Icterohaemorrhagiae, Grippotyphosa, Pomona and Tarassovi: 1 year

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

Pregnancy and lactation:
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:
No adverse events other than those mentioned in section “Adverse events” were observed after the administration of a double dose of vaccine.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Pigs for reproduction:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Decreased activity[3], reduced food intake[3]
Rare (1 to 10 animals / 10,000 animals treated):	Vomiting[4], reddening of the skin[4], tachypnoea (rapid breathing)[4], twitching[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction

[1] The observed mean increase was 0.5 °C (in individual cases the maximum increase was 1.5 °C) up until 2 days after vaccination.
[2] Local reactions, mostly consisting of red, mild to hard, non-painful swellings. In general, local reactions may have a diameter of ≤ 5 cm, and 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.
[3] Feed intake and activity are completely restored within a week.
[4] Intermediate systemic reactions, which resolve in a few minutes.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}. [< > to be adjusted nationally]

8. Dosage for each species, routes 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 *Erysipelothrix rhusiopathiae* containing product should be given to maintain immunity against *Erysipelothrix 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 by multiple broaching.

10. Withdrawal periods

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. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment. Ask your veterinary surgeon how to dispose of medicines no longer required.
[< > to be adjusted nationally]

13. Classification of veterinary medicinal products

[DE-AT-BE-BG-CY-CZ-DK-EE-ES-FR-EL-HR-HU-IT-LT-LU-LV-NL-PL-PT-RO-SI-SK-XI]
Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/3016

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

{[to be completed nationally]}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> < and contact details to report suspected adverse reactions>:
{[< > to be adjusted nationally]}

<Manufacturer responsible for batch release:> {[< > to be adjusted nationally if included in the above]}:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{[< > to be adjusted nationally]}

< Local representative> <and contact details to report suspected adverse reactions>:
{[< > to be adjusted nationally]}

17. Other information

[To be completed nationally where applicable]

Approved 05 October 2023