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 suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Per 2 ml dose:
Inactivated *E. rhusiopathiae* strain M2 (serotype 2): ≥ 1 pig protective dose.
Inactivated PPV strain 014: ≥ 552 EU (antigenic mass ELISA).

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (sows and gilts)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.
Read the package leaflet before use.

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

Read the package leaflet before use.

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

For animal treatment only.

POM-V
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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4334

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park.
Citywest Road, Dublin 24, Ireland

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials of 100/250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Per 2 ml dose:
Inactivated antigen of *Erysipelothrix rhusiopathiae* strain M2: ≥ 1 ppd.
Inactivated PPV strain 014: ≥ 552 EU.

3. PHARMACEUTICAL FORM

Suspension for injection for pigs

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs (sows and gilts)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Intramuscular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous.

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

Once broached, use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton.

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

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

Read the package leaflet before use.

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

For animal treatment only.

POM-V
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4334

17. MANUFACTURER'S BATCH NUMBER

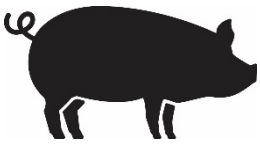
Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 20/50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated antigen of *E. rhusiopathiae* strain M2: ≥ 1 ppd
Inactivated PPV strain 014: ≥ 552 EU

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

20 ml (10 doses)
50 ml (25 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

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.

National requirements:

Keep the vial in the outer carton.

POM-V
To be supplied only on veterinary prescription.

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes,
MK7 7AJ

Vm 01708/4334

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Porcilis Ery+Parvo 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:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis Ery+Parvo suspension for injection for pigs

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

Each dose (2 ml) contains:

Active substances
Inactivated lysed antigen concentrate of *Erysipelothrix rhusiopathiae*, strain M2 (serotype 2): ≥ 1 pig protective dose (ppd)*
Inactivated porcine parvovirus (PPV), strain 014: ≥ 552 EU**
* as measured in the Ph. Eur. potency test
** as determined in the final product by antigenic mass ELISA

Adjuvant
dl-α-tocopherol: 150 mg

Suspension for injection.
Aqueous white or nearly white liquid.

4. INDICATION

For active immunisation of sows and gilts to prevent clinical signs of Erysipelas disease caused by all relevant *Erysipelothrix rhusiopathiae* serotypes (serotype 1 and 2), and for protection against embryonal and foetal death caused by porcine parvovirus (PPV) infection.

E. rhusiopathiae:	Onset of immunity: 3 weeks. Duration of immunity: 6 months.
Porcine parvovirus (PPV):	Duration of immunity: 12 months.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

In laboratory studies and field trials
Transient increases in body temperature (0.5 °C) within 24 hours may very commonly occur.
Mild transient local swelling (Ø 1 – 10 mm) until 8 days after vaccination may very commonly occur.
Transient reluctance to move may commonly occur.

In post marketing experience
In very rare cases, a hypersensitivity reaction may occur.

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 serious 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

Pigs (sows and gilts).

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

Administer one dose of 2 ml by deep intramuscular injection behind the ear.

Primary vaccination course
Protection against *E. rhusiopathiae* and PPV should be achieved in gilts before first mating.
For the induction of protection against erysipelas, a double vaccination as a primary vaccination course is advised. This can be achieved with the monovalent erysipelas vaccine (Porcilis Ery) either 4 weeks before or 4 weeks after use of this combined erysipelas and PPV vaccine.
A single injection not later than 2 weeks before mating is sufficient to protect the following pregnancy from damage due to PPV.
To avoid possible interference from maternal antibodies, the pigs should have reached the age of 6 months before vaccination to ensure efficacy against PPV.

Revaccinations
Revaccinations should be given once a year, supplemented with the administration of the monovalent erysipelas vaccine (Porcilis Ery) 6 months after each use of this Porcilis Ery+Parvo vaccine.

9. ADVICE ON CORRECT ADMINISTRATION

Before use, allow the vaccine to reach room temperature.
Shake well before and regularly during use.
Use sterile vaccination equipment. Avoid introduction of contamination by multiple broaching.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the vial in the outer carton.
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 and carton after ‘EXP:’. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

Special precautions for use in animals:
Sick and weak animals should not be vaccinated.

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 label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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.

Overdose (symptoms, emergency procedures, antidotes):
Reactions observed after administration of a double dose are not different from those observed after administration of a single dose.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, 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

July 2020.

15. OTHER INFORMATION

For animal treatment only.

For the active immunisation of sows and gilts as an aid in the control of swine erysipelas and for the protection of their embryos and foetuses against porcine parvovirus infection. The active substances are a lysate of *E. rhusiopathiae* strain M2 (serotype 2) and inactivated PPV strain 014.

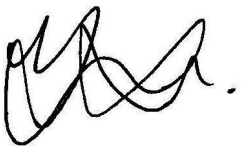
The antigens are incorporated in an aqueous tocopherol-based adjuvant in order to enhance a prolonged stimulation of immunity.

Pack sizes
Cardboard box with one vial of 20 ml (10 doses), 50 ml (25 doses), 100 ml (50 doses) or 250 ml (125 doses).
Not all pack sizes may be marketed.

POM-V To be supplied only on veterinary prescription.

MA number: Vm 01708/4334

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24, Ireland



Approved: 29 September 2020