

## **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):  $\geq 1$  pig protective dose.

Inactivated PPV strain 014:  $\geq 552$  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:  $\geq 1$  ppd.

Inactivated PPV strain 014:  $\geq 552$  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}

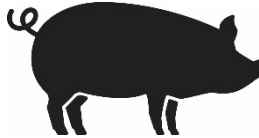


**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

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:  $\geq 1$  ppd  
Inactivated PPV strain 014:  $\geq 552$  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):  $\geq 1$  pig protective dose (ppd)\*

Inactivated porcine parvovirus (PPV), strain 014:  $\geq 552$  EU\*\*

\* as measured in the Ph. Eur. potency test

\*\* as determined in the final product by antigenic mass ELISA

**Adjuvant**

dl- $\alpha$ -tocopherol: 150 mg

Suspension for injection.

Aqueous white or nearly white liquid.



## **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 fetuses 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.

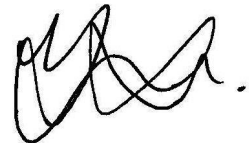
MA number: Vm 01708/4334

Distributor in Northern Ireland

Intervet Ireland Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24, Ireland

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 29 September 2020