PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: Lyophilisate (for intramuscular use)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PRRS lyophilisate for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose (2 ml) $10^{4.0}$ - $10^{6.3}$ $TCID_{50}$ live att. PRRSV

3. PACKAGE SIZE

10 doses
25 doses
50 doses
100 doses
10 x 10 doses
10 x 25 doses
10 x 50 doses
10 x 100 doses

4. TARGET SPECIES

Pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted, use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.

Protect from light.
Keep the vials in the outer box.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5072

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: Solvent (for intramuscular use)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diluvac Forte
Solvent for Porcilis PRRS

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

dl-α-tocopheryl acetate: 75 mg/ml

3. PACKAGE SIZE

20 ml
50 ml
100 ml
200 ml
10 x 20 ml
10 x 50 ml
10 x 100 ml
10 x 200 ml

4. TARGET SPECIES

Pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Keep the vials in the outer box.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5072

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: Combined package (lyophilisate and solvent) for intramuscular use

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PRRS lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose (2 ml) $10^{4.0}$ - $10^{6.3}$ $TCID_{50}$ live att. PRRSV
Solvent: dl-α-tocopheryl acetate: 75 mg/ml

3. PACKAGE SIZE

10 doses
25 doses
50 doses
100 doses
10 x 10 doses
10 x 25 doses
10 x 50 doses
10 x 100 doses

4. TARGET SPECIES

Pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted, use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Protect from light.
Keep the vials in the outer box.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5072

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: Combined package (lyophilisate and solvent) for intradermal use

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PRRS lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose (0.2 ml) $10^{4.0}$ - $10^{6.3}$ $TCID_{50}$ live att. PRRSV
Solvent: dl-α-tocopheryl acetate: 75 mg/ml

3. PACKAGE SIZE

10 doses
25 doses
50 doses
100 doses
5 x 10 doses
5 x 25 doses
5 x 50 doses
5 x 100 doses

4. TARGET SPECIES

Pigs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intradermal use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted, use within 3 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Protect from light.
Keep the vials in the outer box.

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5072

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL: Lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PRRS

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Per dose (2 ml IM / 0.2 ml ID):
$10^{4.0}$ - $10^{6.3}$ $TCID_{50}$ live att. PRRSV

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 3 hours.

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

10 doses
25 doses
50 doses
100 doses

6. ROUTE(S) OF ADMINISTRATION

IM or ID use.

7. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Additional information:
POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT/SOLVENT LABEL

VIAL LABEL: solvent

1. NAME OF THE DILUENT/SOLVENT

Diluvac Forte
Solvent for Porcilis PRRS

2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2 ml
5 ml
10 ml
20 ml
50 ml
100 ml
200 ml

3. ROUTES OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store below 25 °C.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

Exp. {mm/yyyy}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

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

MSD Animal Health logo only

Additional information:

POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Porcilis PRRS lyophilisate and solvent for suspension for injection for pigs

2. COMPOSITION

Each dose of 2 ml (intramuscular injection) or 0.2 ml (intradermal application) of reconstituted vaccine contains:

Lyophilisate:
Active substance:
Live attenuated PRRS virus strain DV: $10^{4.0}$ - $10^{6.3}$ $TCID_{50}$*

Solvent:
Adjuvant:
dl-α-tocopheryl acetate: 75 mg/ml

Lyophilisate: light yellow to white cake.
Solvent: white solution.

*tissue culture infective dose 50%

3. TARGET SPECIES

Pigs

4. INDICATIONS FOR USE

For active immunisation of clinically healthy pigs in a PRRS virus contaminated environment, to reduce viraemia caused by infection with European strains of PRRS virus.

Specific claims
For finishing pigs, the effect of the virus on the respiratory system is most relevant. A significant improvement of rearing results (reduced morbidity due to PRRS infection, and a better daily growth and feed conversion) until the end of the fattening period was observed in vaccinated pigs during field trials, particularly in piglets vaccinated at 6 weeks of age.
For breeding pigs, the effect of the virus on the reproductive system is most relevant. A significant improvement of the reproductive performance in PRRS virus contaminated environments and a reduction of transplacental virus transmission after challenge was observed in vaccinated pigs.

Onset of immunity: 28 days post vaccination.
Duration of immunity: 24 weeks post vaccination.

5. CONTRAINDICATIONS

Do not use in herds where the prevalence of European PRRS virus has not been established through reliable diagnostic methods.

6. SPECIAL WARNING(S)

For animal treatment only.

Special warnings:
No data are available on the safety of the vaccine for the reproductive performance in boars. Do not use in herds where a PRRS eradication programme based on serology has been adopted.

Maternally derived antibodies may interfere with the response to vaccination.

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Care should be taken to avoid the introduction of the vaccine strain into an area where PRRS virus is not already present. The vaccine virus may spread to pigs in contact during 5 weeks after vaccination. The most common spreading route is via direct contact, but spreading via contaminated objects or via the air cannot be excluded. Care should be taken to avoid spread of vaccine virus from vaccinated animals to unvaccinated animals (e.g. naïve pregnant sows) that should remain free from PRRS virus. Do not use in boars producing semen for seronegative herds, as PRRS virus may be excreted in semen for many weeks.

Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

In order to limit the potential risk of recombination between PRRS MLV vaccine strains of the same genotype, do not use different PRRS MLV vaccines based on different strains of the same genotype on the same farm at the same time. In the case of transitioning from one PRRS MLV vaccine to another PRRS MLV vaccine, a transition period should be respected between the last administration of the current vaccine and the first administration of the new vaccine. This transition period should be longer than the shedding period of 5 weeks following vaccination.

PRRS virus-naïve breeding animals (e.g. replacement gilts from PRRS virus-negative herds) which are introduced into a PRRSV-infected herd should be vaccinated prior to first insemination. Vaccination should preferably be done in a separated quarantine unit. A transition period should be respected between vaccination and moving the animals to the breeding unit. This transition period should be longer than the shedding phase of 5 weeks following vaccination.

Vaccination should aim to achieve a homogenous immunity in the target population at farm level.

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.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy:
PRRS virus-naïve gilts and sows should not be vaccinated during pregnancy, as this can have negative effects. Vaccination during pregnancy is safe when it is performed in gilts and sows which are already immunised against European PRRS virus via vaccination or field infection.

Lactation:
Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data for intramuscular injection are available in finishing pigs from 4 weeks of age onwards, which demonstrate that this vaccine can be mixed with Porcilis M Hyo.

Safety and efficacy data are available for both routes of administration in finishing pigs from 3 weeks of age onwards, which demonstrate that this vaccine can be given with Porcilis PCV M Hyo, with Porcilis Lawsonia, or with a mixture of Porcilis PCV M Hyo and Porcilis Lawsonia, at the same time, but at separate sites (preferably at the opposite side of the neck).
In individual pigs the temperature increase after associated use may commonly exceed 2 °C. The temperature returns to normal from 1 to 2 days after the peak temperature is observed. Transient local injection site reactions, which are restricted to a slight injection site lump (maximum 2 cm diameter), may commonly occur from 5 days after vaccination onwards, after intradermal and after intramuscular vaccination. These lumps may occasionally persist until 29 days after vaccination or longer. Hypersensitivity reactions after vaccination may occur uncommonly.

Safety and efficacy data are available in pigs from 3 weeks of age onwards which demonstrate that this vaccine can be administered intradermally non-mixed with Porcilis PCV ID alone or with Porcilis PCV ID mixed with Porcilis Lawsonia ID and/or non-mixed with Porcilis M Hyo ID ONCE providing that administration site of non-mixed vaccines is separated by at least 3 cm. Adverse events are as described in section “Adverse events”, except for injection site lumps of up to 2.5 cm can be observed in individual pigs. These lumps may last 5 weeks and are very commonly accompanied by redness and crusts. Hyperthermia on the day of vaccination (mean 0.3 °C, individual pigs up to 1.2 °C) is common. Lying down and malaise can be uncommonly observed in vaccinated pigs. The product literature of respective products should be consulted before administration in association with Porcilis PRRS. No information is available on the safety and efficacy of the administration of Porcilis PRRS in association with the above-mentioned products in breeding animals or during pregnancy

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, except the products mentioned above. 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:
The effects seen after a ten-fold overdose of vaccine virus and a two-fold overdose of solvent were similar to those seen after a single dose of vaccine.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied with the product or with Porcilis M Hyo.
Do not use with any other veterinary medicinal product except those mentioned in section above.

7. ADVERSE EVENTS

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site lump.[1]
Rare (1 to 10 animals / 10,000 animals treated):	Hyperthermia[2], hypersensitivity reactions (including dyspnoea, hyperaemia, decubitus, muscle tremor, excitation, vomiting).[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reactions.[4]

[1] After intradermal vaccination a small firm injection site lump (maximum 1.5 cm in diameter) is observed and is indicative of the appropriate vaccination technique. This lump is generally seen for less than 14 days but may occasionally persist for 29 days or longer.
[2] After intramuscular vaccination.
[3] These signs disappear spontaneously and totally within a few minutes after vaccination.
[4] Fatal outcome of anaphylactic-type reactions has been reported very rarely.

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.

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

Reconstitute the vaccine with the corresponding adjuvating solvent.

Number of doses per vial	Volume (ml) of solvent needed for	
	intramuscular injection	intradermal application
10	20	2
25	50	5
50	100	10
100	200	20

Before reconstitution allow the solvent to reach room temperature (15 °C – 25 °C) and shake well before use.

Dosage:
Intramuscular injection: 2 ml in the neck.
Intradermal application: 0.2 ml on top or to the left or right side of the neck, or along the muscles of the back, using a multi-dose needle-free injection device for intradermal application of liquids suitable to deliver a “jet-stream” volume of vaccine (0.2 ml ± 10%) through the epidermal layers of the skin.
A small, transient, intradermal lump observed after the intradermal application is indicative of the appropriate vaccination technique.

Vaccination scheme:
A single dose is given to pigs from 2 weeks of age onwards.

Finishing pigs: a single vaccination is sufficient for protection until slaughter.
Breeding pigs: For gilts a (re)vaccination 2-4 weeks before mating is recommended. To maintain a high and homologous level of immunity, revaccination at regular intervals is recommended, either before each next gestation or at random at 4 month intervals. Pregnant sows should only be vaccinated after previous exposure to European PRRS virus.

The vaccine may be reconstituted shortly before vaccination for simultaneous use with Porcilis M Hyo in finishing pigs from 4 weeks of age and the following instructions should be used:

Porcilis PRRS		Porcilis M Hyo
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml
100 doses	+	200 ml

A single dose (2 ml) of Porcilis PRRS mixed with Porcilis M Hyo is given intramuscularly in the neck.

9. ADVICE ON CORRECT ADMINISTRATION

Use sterile syringes and needles or clean intradermal equipment.

Visual appearance after reconstitution: white suspension.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vials in the outer box.

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

Shelf-life after reconstitution according to directions: 3 hours.
Shelf life after mixing with Porcilis M Hyo: 1 hour (at room temperature).

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5072

<u>Presentations for IM use:</u>
Cardboard box with 1 or 10 vial(s) of lyophilisate (10 doses).
Cardboard box with 1 or 10 vial(s) of lyophilisate (25 doses).
Cardboard box with 1 or 10 vial(s) of lyophilisate (50 doses).
Cardboard box with 1 or 10 vial(s) of lyophilisate (100 doses).
Cardboard box with 1 or 10 vial(s) of lyophilisate (10 doses) and 1 or 10 vial(s) of solvent (20 ml).
Cardboard box with 1 or 10 vial(s) of lyophilisate (25 doses) and 1 or 10 vial(s) of solvent (50 ml).
Cardboard box with 1 or 10 vial(s) of lyophilisate (50 doses) and 1 or 10 vial(s) of solvent (100 ml).
Cardboard box with 1 or 10 vial(s) of lyophilisate (100 doses) and 1 or 10 vial(s) of solvent (200 ml).

Cardboard box with 1 or 10 vial(s) of lyophilisate (10 doses) and a cardboard box with 1 or 10 vial(s) of solvent (20 ml).
Cardboard box with 1 or 10 vial(s) of lyophilisate (25 doses) and a cardboard box with 1 or 10 vial(s) of solvent (50 ml).
Cardboard box with 1 or 10 vial(s) of lyophilisate (50 doses) and a cardboard box with 1 or 10 vial(s) of solvent (100 ml).
Cardboard box with 1 or 10 vial(s) of lyophilisate (100 doses) and a cardboard box with 1 or 10 vial(s) of solvent (200 ml).

Presentation for ID use:
Cardboard box with 1 or 5 vial(s) of lyophilisate (10 doses) and 1 or 5 vial(s) of solvent (2 ml).
Cardboard box with 1 or 5 vial(s) of lyophilisate (25 doses) and 1 or 5 vial(s) of solvent (5 ml).
Cardboard box with 1 or 5 vial(s) of lyophilisate (50 doses) and 1 or 5 vial(s) of solvent (10 ml).
Cardboard box with 1 or 5 vial(s) of lyophilisate (100 doses) and 1 or 5 vial(s) of solvent (20 ml).

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 2023

Find more product information by searching for the Product Information Database 'PID' on www.gov.uk.

16. CONTACT DETAILS

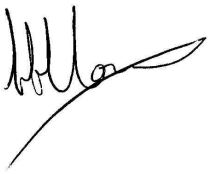
Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ, UK

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

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44(0)1908 685685

17. OTHER INFORMATION

On the basis of antibodies induced by vaccination, it is not possible to discriminate vaccinated animals from those naturally infected with European strains of PRRS virus.



Approved December 2023