ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substances:

Modified live PRRSV-1* strain 96V198: $10^{2.2}$ – $10^{5.2}$ $CCID_{50}$**

* Porcine respiratory and reproductive syndrome virus, genotype 1
** Cell culture infectious dose 50%

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lyophilisate:	
Dextran 40	
Casein hydrolysate	
Lactose monohydrate	
Sorbitol 70% (solution)	
Sodium hydroxide	
Dilution medium	
Solvent:	
Sodium chloride solution for injection	9 mg/ml (0.9%)

Lyophilisate: off-white colour.
Solvent: clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (pigs for fattening, gilts and sows).

3.2 Indications for use for each target species

For active immunisation of clinically healthy pigs from 1 day of age in a porcine respiratory and reproductive syndrome (PRRS) virus-contaminated environment, to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus (genotype 1).

Onset of immunity: 3 weeks.
Duration of immunity: 26 weeks.

Fattening pigs:
In addition, intramuscular vaccination of seronegative 1-day-old piglets was demonstrated to reduce lung lesions against challenge administered at 26 weeks post vaccination. Intramuscular vaccination of seronegative 2-week-old piglets was demonstrated to reduce lung lesions and oral shedding against challenge administered at 28 days and at 16 weeks post-vaccination.

Additionally, nasal vaccination of seronegative 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered at 21 days post-vaccination. Nasal vaccination of seropositive 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered 10 weeks post-vaccination.

Gilts and sows:
In addition, pre-pregnancy vaccination of clinically healthy gilts and sows, non-PRRS virus-naïve (i.e. either previously immunised against PRRS virus via vaccination or exposed to PRRS virus via field infection) or PRRS virus-naïve, was demonstrated to reduce the transplacental infection caused by PRRS virus during the last third of pregnancy, and to reduce the associated negative impact on reproductive performance (reduction of the occurrence of stillbirths, of piglet viraemia at birth and at weaning, of lung lesions and of viral load in lungs in piglets at weaning).

3.3 Contraindications

Do not use in herds where European PRRS virus has not been detected by reliable diagnostic methods.

Do not use in boars producing semen, as PRRS virus can be shed in semen.

Do not use in PRRS virus-naïve pregnant gilts and sows in the second half of gestation because the vaccine strain may cross the placenta. The administration of the vaccine to pregnant PRRS virus-naïve gilts and sows in the second half of gestation may have an impact on their reproductive performance.

3.4 Special warnings

Vaccinate healthy animals only.

Do not vaccinate pigs younger than 3 days by nasal route since the concurrent intake of colostrum may interfere with the efficacy of the vaccine.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccination should aim to achieve a homogenous immunity in the target population at farm level. Care should be taken to avoid the introduction of the vaccine strain into an area where PRRS virus is not already present.

After intramuscular vaccination animals may excrete the vaccine strain for more than 16 weeks. After nasal vaccination animals may excrete the vaccine strain for more than 10 weeks. The vaccine strain can spread to in-contact pigs. The most common spreading route is via direct contact, but spreading via contaminated objects or an airborne spread cannot be excluded.
Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated animals (e.g. PRRS virus-naïve pregnant gilts and sows in the second half of gestation) that should remain free from PRRS virus.

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 the PRRS MLV vaccine following vaccination.

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 the current vaccine following vaccination. Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

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

3.6 Adverse events

Pigs for fattening

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Common (1 to 10 animals / 100 animals treated):	Injection site swelling[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Anaphylactic-type reactions (e.g. vomiting, tremors and/or mild depression)[3]

[1]Transient; observed within 4 days after vaccination. On average 0.5 °C and up to 1.4 °C individually.
[2]In general below 2 cm in diameter; resolves in 3 days.
[3]Observed shortly after vaccination. Resolves without treatment within few hours.

Pre-breeding PRRS virus-naïve gilts and sows

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.2 °C and up to 1.0 °C individually.
[2] In general below 0.5 cm in diameter; resolves spontaneously within 5 days without treatment.

PRRS virus-naïve gilts and sows in the first half of gestation

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.8 °C and up to 1.0 °C individually.
[2]In general, below 1.4 cm in diameter; resolves spontaneously within 9 days without treatment.

Non-PRRS virus-naïve gilts and sows in the second half of gestation

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.4 °C and up to 0.6 °C individually.
[2]In general below 5 cm in diameter; resolves spontaneously within 32 days without treatment.

Lactating sows

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Decreased appetite[2] Injection site swelling[3]

[1]Up to 2.2 ºC. Observed 2 days post vaccination; resolves spontaneously within 4 days without treatment.
[2]Observed 1 - 4 days post vaccination and resolves spontaneously within 3 days without treatment.
[3]Up to 11 cm in diameter; Resolves spontaneously within 3 days without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used in PRRS virus-naïve gilts and sows pre-breeding or in the first half of gestation.
Can be used in non-PRRS virus-naïve gilts and sows in the second half of gestation.

Lactation:
Can be used during lactation.

3.8 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.

3.9 Administration routes and dosage

Method of administration:
Immunisation must be carried out by intramuscular or nasal administration.

Reconstitute the lyophilisate with the supplied solvent. In cases where the vials containing the solvent and the lyophilisate are stored separately, verify prior to reconstituting the lyophilisate that the lot number mentioned on the vial containing the solvent is identical to the lot number mentioned on the vial containing the lyophilisate.

Reconstitute the vaccine with the corresponding solvent:

Number of doses per vial (lyophilisate)	**Volume of solvent needed**
25 ds	50 ml
50 ds	100 ml
125 ds	250 ml

Transfer approximately 5 ml of solvent to the vial containing the lyophilisate and ensure complete reconstitution. Transfer back the reconstituted solution into the solvent vial (containing the remaining solvent): 25 doses are reconstituted into 50 ml solvent, 50 doses are reconstituted into 100 ml solvent, and 125 doses are reconstituted into 250 ml solvent.

After reconstitution, the suspension should be orange colored liquid which might contain a loose resuspendable sediment.

Dosage:
Intramuscular administration: 2 ml in the neck.

Nasal administration: 2 ml administered as 1 ml in each nostril.

Vaccination schedule:
Pigs for fattening from 1 day of age onwards:
A single dose of 2 ml is given to pigs via intramuscular administration.

Pigs for fattening from 3 days of age onwards:
A single dose of 2 ml is given to pigs via intramuscular administration, or a single dose of 2 ml is given to pigs via nasal route by administering 1 ml in each nostril using a sterile syringe not connected to a needle.

Gilts and sows:
A single dose of 2 ml is given via intramuscular administration prior to introduction into the sow herd, approximately 4 weeks prior to breeding. A single booster dose is given every 6 months.

Use sterile syringes and needles.

The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions. Needles for administration should be appropriate for the size of the pig.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Upon administration of a 10-fold overdose in piglets, anaphylactic-type reactions (tremor, apathy and/or vomiting) were very commonly observed shortly after vaccination; these signs resolved without treatment within a few hours. A transient increase in rectal temperature (0.3 °C on average, and up to 1.2 °C individually) very commonly occurred 24 hours post vaccination. Local reactions, in the form of soft/hard swelling (below or equal to 0.7 cm diameter) without heat or pain, were very commonly observed at the injection site and resolved within 5 days.

The administration of a 10-fold overdose to PRRS virus-naïve pre-breeding or pregnant gilts and sows in the first or second half of pregnancy induced similar adverse reactions as those described under section 3.6. The maximum size of the local reactions was bigger (2 cm) and the maximum duration was in general longer (up to 9 days in pre-breeding sows).

After the administration of a 10-fold overdose to non-PRRS virus-naïve gilts and sows in the second half of pregnancy a transient increase in rectal temperature (0.3 °C on average, and up to 0.6 °C individually) occurred 4 hours post vaccination. A local reaction involving transiently the whole neck region was very commonly observed (red-purple dark, erythematous swelling, causing itching, vesicle formation, increased local temperature, and, occasionally, pain). The reaction evolved to form hard tissue and formation of a scab, which very commonly lasted up to more than 44 days.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AD03

The vaccine contains a modified live PRRS virus (genotype 1, subtype-1). It stimulates active immunity against PRRS virus. Vaccine efficacy has been demonstrated in laboratory vaccination and challenge studies using a genotype 1, subtype-1 strain.

Additional clinical studies demonstrated that intramuscular vaccination of seronegative 1-day-old piglets conferred protection against another subtype-1 strain (AUT15-33), a subtype-2 strain (BOR57) and a subtype-3 strain (Lena) of PRRS virus genotype 1.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
The solvent may be stored outside a refrigerator at 15 °C – 25 °C.
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Vaccine (lyophilisate):
Type 1 hydrolytic glass vials of 15 ml (25, 50 or 125 doses), with a bromobutyl elastomer closure and sealed with an aluminium cap.

Solvent:
High-density polyethylene (HDPE) vials of 50, 100 or 250 ml of solvent, with a chlorobutyl elastomer closure and sealed with an aluminium cap.
Cardboard box of 1 vial of 15 ml (25 doses) and 1 vial of 50 ml of solvent.
Cardboard box of 1 vial of 15 ml (50 doses) and 1 vial of 100 ml of solvent.
Cardboard box of 1 vial of 15 ml (125 doses) and 1 vial of 250 ml of solvent.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/215/001–003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24/08/2017.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml dose contains:

Active substances:

Modified live PRRSV-1* strain 96V198: $10^{2.2}$ – $10^{5.2}$ $CCID_{50}$**

* Porcine respiratory and reproductive syndrome virus, genotype 1
** Cell culture infectious dose 50%

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lyophilisate:	
Dextran 40	
Casein hydrolysate	
Lactose monohydrate	
Sorbitol 70% (solution)	
Sodium hydroxide	
Dilution medium	
Solvent:	
Sodium chloride solution for injection	9 mg/ml (0.9%)

Lyophilisate: off-white colour.
Solvent: clear, colourless solution.

3. CLINICAL INFORMATION

3.1. Target species

Pigs (pigs for fattening, gilts and sows).

3.2 Indications for use for each target species

For active immunisation of clinically healthy pigs from 1 day of age in a porcine respiratory and reproductive syndrome (PRRS) virus-contaminated environment, to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus (genotype 1).

Onset of immunity: 3 weeks.
Duration of immunity: 26 weeks.

Fattening pigs:
In addition, intramuscular vaccination of seronegative 1-day-old piglets was demonstrated to reduce lung lesions against challenge administered at 26 weeks post vaccination. Intramuscular vaccination of seronegative 2-week-old piglets was demonstrated to reduce lung lesions and oral shedding against challenge administered at 28 days and at 16 weeks post-vaccination.

Additionally, nasal vaccination of seronegative 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered at 21 days post-vaccination. Nasal vaccination of seropositive 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered 10 weeks post-vaccination.

Gilts and sows:
In addition, pre-pregnancy vaccination of clinically healthy gilts and sows, non-PRRS virus-naïve (i.e. either previously immunised against PRRS virus via vaccination or exposed to PRRS virus via field infection) or PRRS virus-naïve, was demonstrated to reduce the transplacental infection caused by PRRS virus during the last third of pregnancy, and to reduce the associated negative impact on reproductive performance (reduction of the occurrence of stillbirths, of piglet viraemia at birth and at weaning, of lung lesions and of viral load in lungs in piglets at weaning).

3.3 Contraindications

Do not use in herds where European PRRS virus has not been detected by reliable diagnostic methods.

Do not use in boars producing semen, as PRRS virus can be shed in semen.

Do not use in PRRS virus-naïve pregnant gilts and sows in the second half of gestation because the vaccine strain may cross the placenta. The administration of the vaccine to pregnant PRRS virus-naïve gilts and sows in the second half of gestation may have an impact on their reproductive performance.

3.4 Special warnings

Vaccinate healthy animals only.

Do not vaccinate pigs younger than 3 days by nasal route since the concurrent intake of colostrum may interfere with the efficacy of the vaccine.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccination should aim to achieve a homogenous immunity in the target population at farm level. Care should be taken to avoid the introduction of the vaccine strain into an area where PRRS virus is not already present.

After intramuscular vaccination animals may excrete the vaccine strain for more than 16 weeks. After nasal vaccination animals may excrete the vaccine strain for more than 10 weeks. The vaccine strain can spread to in-contact pigs. The most common spreading route is via direct contact, but spreading via contaminated objects or an airborne spread cannot be excluded.
Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated animals (e.g. PRRS virus-naïve pregnant gilts and sows in the second half of gestation) that should remain free from PRRS virus.

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 the PRRS MLV vaccine following vaccination.

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 the current vaccine following vaccination. Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

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

3.6 Adverse events

Pigs for fattening

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Common (1 to 10 animals / 100 animals treated):	Injection site swelling[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Anaphylactic-type reactions (e.g. vomiting, tremors and/or mild depression)[3]

[1]Transient; observed within 4 days after vaccination. On average 0.5 °C and up to 1.4 °C individually.
[2]In general below 2 cm in diameter; resolves in 3 days.
[3]Observed shortly after vaccination. Resolves without treatment within few hours.

Pre-breeding PRRS virus-naïve gilts and sows

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.2 °C and up to 1.0 °C individually.
[2] In general below 0.5 cm in diameter; resolves spontaneously within 5 days without treatment.

PRRS virus-naïve gilts and sows in the first half of gestation

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.8 °C and up to 1.0 °C individually.
[2]In general, below 1.4 cm in diameter; resolves spontaneously within 9 days without treatment.

Non-PRRS virus-naïve gilts and sows in the second half of gestation

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.4 °C and up to 0.6 °C individually.
[2]In general below 5 cm in diameter; resolves spontaneously within 32 days without treatment.

Lactating sows

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Decreased appetite[2] Injection site swelling[3]

[1]Up to 2.2 ºC. Observed 2 days post vaccination; resolves spontaneously within 4 days without treatment.
[2]Observed 1 - 4 days post vaccination and resolves spontaneously within 3 days without treatment.
[3]Up to 11 cm in diameter; Resolves spontaneously within 3 days without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used in PRRS virus-naïve gilts and sows pre-breeding or in the first half of gestation.
Can be used in non-PRRS virus-naïve gilts and sows in the second half of gestation.

Lactation:
Can be used during lactation.

3.8 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.

3.9 Administration routes and dosage

Method of administration:
Immunisation must be carried out by intramuscular or nasal administration.

Reconstitute the lyophilisate with the supplied solvent. In cases where the vials containing the solvent and the lyophilisate are stored separately, verify prior to reconstituting the lyophilisate that the lot number mentioned on the vial containing the solvent is identical to the lot number mentioned on the vial containing the lyophilisate.

Reconstitute the vaccine with the corresponding solvent:

Number of doses per vial (lyophilisate)	**Volume of solvent needed**
100 ds	50 ml

Transfer approximately 5 ml of solvent to the vial containing the lyophilisate and ensure complete reconstitution. Transfer back the reconstituted solution into the solvent vial (containing the remaining solvent): 100 doses are reconstituted into 50 ml solvent.

After reconstitution, the suspension should be orange colored liquid which might contain a loose resuspendable sediment.

Dosage:
Intramuscular administration: 0.5 ml in the neck.
Nasal administration: 0.5 ml administered in one nostril.

Vaccination schedule:

Pigs for fattening from 1 day of age onwards:
A single dose of 0.5 ml is given to pigs via intramuscular administration.

Pigs for fattening from 3 days of age onwards:
A single dose of 0.5 ml is given to pigs via intramuscular administration, or a single dose of 0.5 ml is given to pigs via nasal route by administration in one nostril using a sterile syringe not connected to a needle.

Gilts and sows:
A single dose of 0.5 ml is given via intramuscular administration prior to introduction into the sow herd, approximately 4 weeks prior to breeding. A single booster dose is given every 6 months.

Use sterile syringes and needles.

The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions. Needles for administration should be appropriate for the size of the pig.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Upon administration of a 10-fold overdose in piglets, anaphylactic-type reactions (tremor, apathy and/or vomiting) were very commonly observed shortly after vaccination; these signs resolved without treatment within a few hours. A transient increase in rectal temperature (0.3 °C on average, and up to 1.2 °C individually) very commonly occurred 24 hours post vaccination. Local reactions, in the form of soft/hard swelling (below or equal to 0.7 cm diameter) without heat or pain, were very commonly observed at the injection site and resolved within 5 days.

The administration of a 10-fold overdose to PRRS virus-naïve pre-breeding or pregnant gilts and sows in the first or second half of pregnancy induced similar adverse reactions as those described under section 3.6. The maximum size of the local reactions was bigger (2 cm) and the maximum duration was in general longer (up to 9 days in pre-breeding sows).

After the administration of a 10-fold overdose to non-PRRS virus-naïve gilts and sows in the second half of pregnancy a transient increase in rectal temperature (0.3 °C on average, and up to 0.6 °C individually) occurred 4 hours post vaccination. A local reaction involving transiently the whole neck region was very commonly observed (red-purple dark, erythematous swelling, causing itching, vesicle formation, increased local temperature, and, occasionally, pain). The reaction evolved to form hard tissue and formation of a scab, which very commonly lasted up to more than 44 days.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AD03

The vaccine contains a modified live PRRS virus (genotype 1, subtype-1). It stimulates active immunity against PRRS virus. Vaccine efficacy has been demonstrated in laboratory vaccination and challenge studies using a genotype 1, subtype-1 strain.

Additional clinical studies demonstrated that intramuscular vaccination of seronegative 1-day-old piglets conferred protection against another subtype-1 strain (AUT15-33), a subtype-2 strain (BOR57) and a subtype-3 strain (Lena) of PRRS virus genotype 1.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
The solvent may be stored outside a refrigerator at 15 °C – 25 °C.
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Vaccine (lyophilisate):
Type 1 hydrolytic glass vials of 15 ml (100 doses), with a bromobutyl elastomer closure and sealed with an aluminium cap.

Solvent:
High-density polyethylene (HDPE) vials of 50 ml of solvent, with a chlorobutyl elastomer closure and sealed with an aluminium cap.

Cardboard box of 1 vial of 15 ml (100 doses) and 1 vial of 50 ml of solvent.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/215/004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 24/08/2017.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (25, 50 AND 125 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV Lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Modified live PRRSV-1, strain 96V198: $10^{2.2}$ – $10^{5.2}$ $CCID_{50}$

3. PACKAGE SIZE

Lyophilisate (1 x 25 doses) + solvent (1 x 50 ml)
Lyophilisate (1 x 50 doses) + solvent (1 x 100 ml)
Lyophilisate (1 x 125 doses) + solvent (1 x 250 ml)

4. TARGET SPECIES

Pigs (pigs for fattening, gilts and sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or nasal use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
The solvent may be stored outside 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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/215/001 lyophilisate (1 x 25 doses) + solvent (1 x 50 ml)
EU/2/17/215/002 lyophilisate (1 x 50 doses) + solvent (1 x 100 ml)
EU/2/17/215/003 lyophilisate (1 x 125 doses) + solvent (1 x 250 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (100 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV Lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.5 ml dose contains:
Modified live PRRSV-1, strain 96V198: $10^{2.2}$ – $10^{5.2}$ $CCID_{50}$

3. PACKAGE SIZE

Lyophilisate (1 x 100 doses) + solvent (1 x 50 ml)

4. TARGET SPECIES

Pigs (pigs for fattening, gilts and sows).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular or nasal use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
The solvent may be stored outside 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

Zoetis Belgium

14. MARKETING AUTHORISATION NUMBERS

EU/2/17/215/004 lyophilisate (1 x 100 doses) + solvent (1 x 50 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SOLVENT HDPE VIALS (100 ML OR 250 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV Solvent

2. STATEMENT OF ACTIVE SUBSTANCES

Sodium chloride 0.9% solution

50 doses (2 ml)
125 doses (2 ml)

3. TARGET SPECIES

Pigs (pigs for fattening, gilts and sows).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

The solvent may be stored outside a refrigerator.
Do not freeze. Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SOLVENT HDPE VIALS (50 ML)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV Solvent

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Sodium chloride 0.9% solution

25 doses (2 ml)
100 doses (0.5 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached and reconstituted use immediately.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LYOPHILISATE GLASS VIALS (15 ML, CONTAINING 25, 50, 100, OR 125 DOSES)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV Lyophilisate

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Modified live PRRSV-1, strain 96V198: $10^{2.2} – 10^{5.2}$ $CCID_{50}$

2 ml
0.5 ml

25 doses (2 ml)
50 doses (2 ml)
100 doses (0.5 ml)
125 doses (2 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached and reconstituted use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substances:
Lyophilisate:
Modified live PRRSV-1*, strain 96V198: $10^{2.2}$ – $10^{5.2}$ $CCID_{50}$**

* Porcine respiratory and reproductive syndrome virus, genotype 1
** Cell culture infectious dose 50%

Solvent:
Sodium chloride 0.9% solution: qs 1 dose.

Lyophilisate: off-white colour.
Solvent: clear, colourless solution.

3. Target species

Pigs (pigs for fattening, gilts and sows).

4. Indications for use

For active immunisation of clinically healthy pigs from 1 day of age in a porcine respiratory and reproductive syndrome (PRRS) virus-contaminated environment, to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus (genotype 1).

Onset of immunity: 3 weeks.

Duration of immunity: 26 weeks.

Fattening pigs:
In addition, intramuscular vaccination of seronegative 1-day-old piglets was demonstrated to reduce lung lesions against challenge administered at 26 weeks post vaccination. Intramuscular vaccination of seronegative 2-week-old piglets was demonstrated to reduce lung lesions and oral shedding against challenge administered at 28 days and at 16 weeks post-vaccination.

Additionally, nasal vaccination of seronegative 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered at 21 days post-vaccination. Nasal vaccination of seropositive 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered 10 weeks post-vaccination.

Gilts and sows:
In addition, pre-pregnancy vaccination of clinically healthy gilts and sows, non-PRRS virus-naïve (i.e. either previously immunised against PRRS virus via vaccination or exposed to PRRS virus via field infection) or PRRS virus-naïve, was demonstrated to reduce the transplacental infection caused by PRRS virus during the last third of pregnancy, and to reduce the associated negative impact on reproductive performance (reduction of the occurrence of stillbirths, of piglet viraemia at birth and at

weaning, of lung lesions and of viral load in lungs in piglets at weaning).

5. Contraindications

Do not use in herds where European PRRS virus has not been detected by reliable diagnostic methods.

Do not use in boars producing semen, as PRRS virus can be shed in semen.

Do not use in PRRS virus-naïve pregnant gilts and sows in the second half of gestation because the vaccine strain may cross the placenta. The administration of the vaccine to pregnant PRRS virus-naïve gilts and sows in the second half of gestation may have an impact on their reproductive performance.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Do not vaccinate pigs younger than 3 days by nasal route since the concurrent intake of colostrum may interfere with the efficacy of the vaccine.

Vaccination should aim to achieve a homogenous immunity in the target population at farm level. Care should be taken to avoid the introduction of the vaccine strain into an area where PRRS virus is not already present.

After intramuscular vaccination animals may excrete the vaccine strain for more than 16 weeks. After nasal vaccination animals may excrete the vaccine strain for more than 10 weeks. The vaccine strain can spread to in-contact pigs. The most common spreading route is via direct contact but spreading via contaminated objects or an airborne spread cannot be excluded.

Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated animals (e.g. PRRS virus-naïve pregnant gilts and sows in the second half of gestation) that should remain free from PRRS virus.

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 the PRRS MLV vaccine following vaccination.
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 the current vaccine following vaccination. Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

Pregnancy:
Can be used in PRRS virus-naïve gilts and sows pre-breeding or in the first half of pregnancy.
Can be used in non-PRRS virus-naive gilts and sows in the second half of pregnancy.

Lactation:
Can be used during 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:
Upon administration of a 10-fold overdose in piglets, anaphylactic-type reactions (tremor, apathy and/or vomiting) were very commonly observed shortly after vaccination; these signs resolved without treatment within a few hours. A transient increase in rectal temperature (0.3 ºC on average, and up to 1.2 °C individually) very commonly occurred 24 hours post vaccination. Local reactions, in the form of soft/hard swelling (below or equal to 0.7 cm diameter) without heat or pain, were very commonly observed at the injection site and resolved within 5 days.

The administration of a 10-fold overdose to PRRS virus-naïve pre-breeding or pregnant gilts and sows in the first or second half of pregnancy induced similar adverse reactions as those described under section 7. The maximum size of the local reactions was bigger (2 cm) and the maximum duration was in general longer (up to 9 days in pre-breeding sows).

After the administration of a 10-fold overdose to non-PRRS virus-naive gilts and sows in the second half of pregnancy a transient increase in rectal temperature (0.3 ºC on average, and up to 0.6 °C individually) occurred 4 hours post vaccination. A local reaction involving transiently the whole neck region was very commonly observed (red-purple dark, erythematous swelling, causing itching, vesicle formation, increased local temperature, and, occasionally, pain). The reaction evolved to form hard tissue and formation of a scab, which very commonly lasted up to more than 44 days.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

7. Adverse events

Pigs for fattening:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Common (1 to 10 animals / 100 animals treated):	Injection site swelling[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Anaphylactic-type reactions (e.g. vomiting, tremors and/or mild depression)[3]

[1]Transient; observed within 4 days after vaccination. On average 0.5 °C and up to 1.4 °C individually.
[2]In general below 2 cm in diameter; resolves in 3 days.
[3]Observed shortly after vaccination. Resolves without treatment within few hours.

Pre-breeding PRRS virus-naïve gilts and sows:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.2 °C and up to 1.0 °C individually.
[2]In general below 0.5 cm in diameter; resolves spontaneously within 5 days without treatment.

PRRS virus-naïve gilts and sows in the first half of gestation:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.8 °C and up to 1.0 °C individually.
[2]In general below 1.4 cm in diameter; resolves spontaneously within 9 days without treatment.

Non-PRRS virus-naïve gilts and sows in the second half of gestation:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.4 °C and up to 0.6 °C individually.
[2] In general below 5 cm in diameter; resolves spontaneously within 32 days without treatment.

Lactating sows:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Decreased appetite[2] Injection site swelling[3]

[1]Up to 2.2 ºC. Observed 2 days post vaccination; resolves spontaneously within 4 days without treatment.
[2]Observed 1 - 4 days post vaccination and resolves spontaneously within 3 days without treatment.
[3]Up to 11 cm in diameter; resolves spontaneously within 3 days without treatment.

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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular administration: 2 ml in the neck.
Nasal administration: 2 ml administered as 1 ml in each nostril.

Pigs for fattening from 1 day of age onwards:
A single dose of 2 ml is given to pigs via intramuscular administration.

Pigs for fattening from 3 days of age onwards:
A single dose of 2 ml is given to pigs via intramuscular administration, or a single dose of 2 ml is given to pigs via nasal route by administering 1 ml in each nostril using a sterile syringe not connected to a needle.

Gilts and sows:
A single dose of 2 ml is given via intramuscular administration prior to introduction into the sow herd, approximately 4 weeks prior to breeding. A single booster dose is given every 6 months.

9. Advice on correct administration

Reconstitute the lyophilisate with the supplied solvent. In cases where the vials containing the solvent and the lyophilisate are stored separately, verify prior to reconstituting the lyophilisate that the lot number mentioned on the vial containing the solvent is identical to the lot number mentioned on the vial containing the lyophilisate.

Reconstitute the vaccine with the corresponding solvent:

Number of doses per vial (lyophilisate)	Volume of solvent needed
25 ds	50 ml
50 ds	100 ml
125 ds	250 ml

Transfer approximately 5 ml of solvent to the vial containing the lyophilisate and ensure complete reconstitution. Transfer back the reconstituted solution into the solvent vial (containing the remaining solvent): 25 doses are reconstituted into 50 ml solvent, 50 doses are reconstituted into 100 ml solvent, and 125 doses are reconstituted into 250 ml solvent.

After reconstitution, the suspension should be orange colored liquid which might contain a loose resuspendable sediment.

Use sterile syringes and needles.

The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions.

Needles for administration should be appropriate for the size of the pig.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
The solvent may be stored outside a refrigerator at 15 °C – 25 °C.
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/215/001-003

Cardboard box of 1 vial of 15 ml (25 doses) and 1 vial of 50 ml of solvent.
Cardboard box of 1 vial of 15 ml (50 doses) and 1 vial of 100 ml of solvent. Cardboard box of 1 vial of 15 ml (125 doses) and 1 vial of 250 ml of solvent.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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, manufacturer responsible for batch release and contact details to report suspected adverse events:

Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

België/Belgique/Belgien
Tél/Tel: +32 (0) 800 99 189
pharmvig-belux@zoetis.com

Република България
Тел: +359 888 51 30 30
zoetisromania@zoetis.com

Česká republika
Tel: +420 257 101 111
infovet.cz@zoetis.com

Danmark
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Deutschland
Tel: +49 30 2020 0049
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Lietuva
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Malta
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adr.scandinavia@zoetis.com

United Kingdom (Northern Ireland)
Tel: +353 (0) 1 256 9800
pvsupportireland@zoetis.com

17. Other information

The vaccine contains a modified live PRRS virus (genotype 1, subtype-1). It stimulates active immunity against PRRS virus. Vaccine efficacy has been demonstrated in laboratory vaccination and challenge studies using a genotype 1, subtype-1 strain.

Additional clinical studies demonstrated that intramuscular vaccination of seronegative 1-day-old piglets conferred protection against another subtype-1 strain (AUT15-33), a subtype-2 strain (BOR57) and a subtype-3 strain (Lena) of PRRS virus genotype 1.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Suvaxyn PRRS MLV lyophilisate and solvent for suspension for injection for pigs

2. Composition

Each 0.5 ml dose contains:

Active substances:
Lyophilisate:
Modified live PRRSV-1*, strain 96V198: $10^{2.2}$ – $10^{5.2}$ $CCID_{50}$**

* Porcine respiratory and reproductive syndrome virus, genotype 1
** Cell culture infectious dose 50%

Solvent:
Sodium chloride 0.9% solution: qs 1 dose.

Lyophilisate: off-white colour.
Solvent: clear, colourless solution.

3. Target species

Pigs (pigs for fattening, gilts and sows).

4. Indications for use

For active immunisation of clinically healthy pigs from 1 day of age in a porcine respiratory and reproductive syndrome (PRRS) virus-contaminated environment, to reduce viraemia and nasal shedding caused by infection with European strains of PRRS virus (genotype 1).

Onset of immunity: 3 weeks.

Duration of immunity: 26 weeks.

Fattening pigs:
In addition, intramuscular vaccination of seronegative 1-day-old piglets was demonstrated to reduce lung lesions against challenge administered at 26 weeks post vaccination. Intramuscular vaccination of seronegative 2-week-old piglets was demonstrated to reduce lung lesions and oral shedding against challenge administered at 28 days and at 16 weeks post-vaccination.

Additionally, nasal vaccination of seronegative 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered at 21 days post-vaccination. Nasal vaccination of seropositive 3-day-old piglets reduced viraemia, nasal shedding and lung lesions against challenge administered 10 weeks post-vaccination.

Gilts and sows:
In addition, pre-pregnancy vaccination of clinically healthy gilts and sows, non-PRRS virus-naïve (i.e. either previously immunised against PRRS virus via vaccination or exposed to PRRS virus via field infection) or PRRS virus-naïve, was demonstrated to reduce the transplacental infection caused by PRRS virus during the last third of pregnancy, and to reduce the associated negative impact on reproductive performance (reduction of the occurrence of stillbirths, of piglet viraemia at birth and at

weaning, of lung lesions and of viral load in lungs in piglets at weaning).

5. Contraindications

Do not use in herds where European PRRS virus has not been detected by reliable diagnostic methods.

Do not use in boars producing semen, as PRRS virus can be shed in semen.

Do not use in PRRS virus-naïve pregnant gilts and sows in the second half of gestation because the vaccine strain may cross the placenta. The administration of the vaccine to pregnant PRRS virus-naïve gilts and sows in the second half of gestation may have an impact on their reproductive performance.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Do not vaccinate pigs younger than 3 days by nasal route since the concurrent intake of colostrum may interfere with the efficacy of the vaccine.

Vaccination should aim to achieve a homogenous immunity in the target population at farm level. Care should be taken to avoid the introduction of the vaccine strain into an area where PRRS virus is not already present.

After intramuscular vaccination animals may excrete the vaccine strain for more than 16 weeks. After nasal vaccination animals may excrete the vaccine strain for more than 10 weeks. The vaccine strain can spread to in-contact pigs. The most common spreading route is via direct contact but spreading via contaminated objects or an airborne spread cannot be excluded.

Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated animals (e.g. PRRS virus-naïve pregnant gilts and sows in the second half of gestation) that should remain free from PRRS virus.

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 the PRRS MLV vaccine following vaccination.
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 the current vaccine following vaccination. Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

Pregnancy:
Can be used in PRRS virus-naïve gilts and sows pre-breeding or in the first half of pregnancy.
Can be used in non-PRRS virus-naive gilts and sows in the second half of pregnancy.

Lactation:
Can be used during 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:
Upon administration of a 10-fold overdose in piglets, anaphylactic-type reactions (tremor, apathy and/or vomiting) were very commonly observed shortly after vaccination; these signs resolved without treatment within a few hours. A transient increase in rectal temperature (0.3 ºC on average, and up to 1.2 °C individually) very commonly occurred 24 hours post vaccination. Local reactions, in the form of soft/hard swelling (below or equal to 0.7 cm diameter) without heat or pain, were very commonly observed at the injection site and resolved within 5 days.

The administration of a 10-fold overdose to PRRS virus-naïve pre-breeding or pregnant gilts and sows in the first or second half of pregnancy induced similar adverse reactions as those described under section 7. The maximum size of the local reactions was bigger (2 cm) and the maximum duration was in general longer (up to 9 days in pre-breeding sows).

After the administration of a 10-fold overdose to non-PRRS virus-naive gilts and sows in the second half of pregnancy a transient increase in rectal temperature (0.3 ºC on average, and up to 0.6 °C individually) occurred 4 hours post vaccination. A local reaction involving transiently the whole neck region was very commonly observed (red-purple dark, erythematous swelling, causing itching, vesicle formation, increased local temperature, and, occasionally, pain). The reaction evolved to form hard tissue and formation of a scab, which very commonly lasted up to more than 44 days.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product.

7. Adverse events

Pigs for fattening:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]
Common (1 to 10 animals / 100 animals treated):	Injection site swelling[2]
Uncommon (1 to 10 animals / 1,000 animals treated):	Anaphylactic-type reactions (e.g. vomiting, tremors and/or mild depression)[3]

[1]Transient; observed within 4 days after vaccination. On average 0.5 °C and up to 1.4 °C individually.
[2]In general below 2 cm in diameter; resolves in 3 days.
[3]Observed shortly after vaccination. Resolves without treatment within few hours.

Pre-breeding PRRS virus-naïve gilts and sows:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.2 °C and up to 1.0 °C individually.
[2]In general below 0.5 cm in diameter; resolves spontaneously within 5 days without treatment.

PRRS virus-naïve gilts and sows in the first half of gestation:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1]Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.8 °C and up to 1.0 °C individually.
[2]In general below 1.4 cm in diameter; resolves spontaneously within 9 days without treatment.

Non-PRRS virus-naïve gilts and sows in the second half of gestation:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Injection site swelling[2]

[1]Transient; observed 4 hours post vaccination. On average 0.4 °C and up to 0.6 °C individually.
[2] In general below 5 cm in diameter; resolves spontaneously within 32 days without treatment.

Lactating sows:

Very common (>1 animal / 10 animals treated):	Elevated temperature[1] Decreased appetite[2] Injection site swelling[3]

[1]Up to 2.2 ºC. Observed 2 days post vaccination; resolves spontaneously within 4 days without treatment.
[2]Observed 1 - 4 days post vaccination and resolves spontaneously within 3 days without treatment.
[3]Up to 11 cm in diameter; resolves spontaneously within 3 days without treatment.

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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular administration: 0.5 ml in the neck.
Nasal administration: 0.5 ml administered in one nostril.

Pigs for fattening from 1 day of age onwards:
A single dose of 0.5 ml is given to pigs via intramuscular administration.

Pigs for fattening from 3 days of age onwards:
A single dose of 0.5 ml is given to pigs via intramuscular administration, or a single dose of 0.5 ml is given to pigs via nasal route by administration in one nostril using a sterile syringe not connected to a needle.

Gilts and sows:
A single dose of 0.5 ml is given via intramuscular administration prior to introduction into the sow herd, approximately 4 weeks prior to breeding. A single booster dose is given every 6 months.

9. Advice on correct administration

Reconstitute the lyophilisate with the supplied solvent. In cases where the vials containing the solvent and the lyophilisate are stored separately, verify prior to reconstituting the lyophilisate that the lot number mentioned on the vial containing the solvent is identical to the lot number mentioned on the vial containing the lyophilisate.

Reconstitute the vaccine with the corresponding solvent:

Number of doses per vial (lyophilisate)	Volume of solvent needed
100 ds	50 ml

Transfer approximately 5 ml of solvent to the vial containing the lyophilisate and ensure complete reconstitution. Transfer back the reconstituted solution into the solvent vial (containing the remaining solvent): 100 doses are reconstituted into 50 ml solvent.

After reconstitution, the suspension should be orange colored liquid which might contain a loose resuspendable sediment.

Use sterile syringes and needles.

The use of a multi-dosing syringe is recommended. Use vaccination devices according to the manufacturer's instructions.

Needles for administration should be appropriate for the size of the pig.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
The solvent may be stored outside a refrigerator at 15 °C – 25 °C.
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: use immediately.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/17/215/004

Cardboard box of 1 vial of 15 ml (100 doses) and 1 vial of 50 ml of solvent.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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, manufacturer responsible for batch release and contact details to report suspected adverse events:

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Belgium

België/Belgique/Belgien
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pharmvig-belux@zoetis.com

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17. Other information

The vaccine contains a modified live PRRS virus (genotype 1, subtype-1). It stimulates active immunity against PRRS virus. Vaccine efficacy has been demonstrated in laboratory vaccination and challenge studies using a genotype 1, subtype-1 strain.

Additional clinical studies demonstrated that intramuscular vaccination of seronegative 1-day-old piglets conferred protection against another subtype-1 strain (AUT15-33), a subtype-2 strain (BOR57) and a subtype-3 strain (Lena) of PRRS virus genotype 1.