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 dose (2 ml) contains:

Lyophilisate:
Active substance:
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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: off-white freeze-dried pellet.

Solvent: clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (pigs for fattening, gilts and sows)

4.2 Indications for use, specifying the 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: 21 days after vaccination.

Duration of immunity: 26 weeks after vaccination.

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).

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals:
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.
Animals vaccinated via intramuscular route may excrete the vaccine strain for more than 16 weeks following vaccination. Animals vaccinated via nasal route 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:
None.

4.6 Adverse reactions (frequency and seriousness)

A transient increase in rectal temperature (0.5 °C on average, and up to 1.4 °C individually) may very commonly occur within 4 days after vaccination. Local reactions in the form of swellings are common and resolve spontaneously within 3 days. The area of local tissue reaction is in general below 2 cm in diameter. Anaphylactic-type reactions (vomiting, tremors and/or mild depression) may uncommonly occur in piglets shortly after vaccination. These resolve without treatment within few hours.

A minor and transient increase in rectal temperature (0.2 °C on average, and up to 1.0 °C individually) may very commonly occur 4 hours post vaccination in pre-breeding PRRS virus-naïve gilts and sows. Local reactions in the form of swellings are very common and resolve spontaneously within 5 days. The area of local tissue reaction is in general below 0.5 cm in diameter.

A minor and transient increase in rectal temperature (0.8 °C on average, and up to 1.0 °C individually) may very commonly occur 4 hours post vaccination in PRRS virus-naïve gilts and sows in the first half of gestation. Local reactions in the form of swellings are very common and resolve spontaneously within 9 days. The area of local tissue reaction is in general below 1.4 cm in diameter.

A minor and transient increase in rectal temperature (0.4 °C on average, and up to 0.6 °C individually) may very commonly occur 4 hours post vaccination in non-PRRS virus-naïve gilts and sows in the second half of gestation. Local reactions in the form of swellings are very common and resolve spontaneously within 32 days. The area of local tissue reaction is in general below 5 cm in diameter.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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:
The safety of the vaccine has not been established during lactation.

4.8 Interactions 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.

4.9 Amounts to be administered and administration route

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. 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.

Dosage:
Intramuscular injection: 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 intramuscularly 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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 4.6. 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.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, live viral vaccines.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Dextran 40
Casein hydrolysate
Lactose monohydrate
Sorbitol 70% (solution)
Sodium hydroxide
Water for injections
Dilution medium

Solvent:
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 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.
For storage conditions of the reconstituted medicinal product, see section 6.3.
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Vaccine (lyophilisate):
Ph. Eur. 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste material derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with the local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBERS

EU/2/17/215/001–003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24/08/2017.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, 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.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance:

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

Name and address of the manufacturer responsible for batch release:

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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 for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

25 doses
50 doses
125 doses

5. TARGET SPECIES

Pigs (pigs for fattening, gilts and sows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Nasal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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

For animal treatment only.
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

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/215/001 (50 ml)
EU/2/17/215/002 (100 ml)
EU/2/17/215/003 (250 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE vials (100 ml or 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV solvent for suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Sodium chloride 0.9% solution

3. PHARMACEUTICAL FORM

Solvent for suspension for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pigs (pigs for fattening, gilts and sows).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
Nasal use

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

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

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

For animal treatment only.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/215/002 100 ml
EU/2/17/215/003 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

HDPE vials (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV solvent for suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Sodium chloride 0.9% solution

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

IM
Nasal use

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials (15 ml, containing 25, 50 or 125 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn PRRS MLV lyophilisate for suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCES

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

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

25 doses
50 doses
125 doses

4. ROUTE(S) OF ADMINISTRATION

IM
Nasal use

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Suvaxyn PRRS MLV lyophilisate and solvent for 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 and manufacturer responsible for batch release:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each dose (2 ml) contains:

Lyophilisate:
Active substance:
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 freeze-dried pellet.
Solvent: clear, colourless solution.

4. INDICATION(S)

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: 21 days after vaccination.

Duration of immunity: 26 weeks after vaccination.

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. ADVERSE REACTIONS

A transient increase in rectal temperature (0.5 °C on average, and up to 1.4 °C individually) may very commonly occur within 4 days after vaccination. Local reactions in the form of swellings are common and resolve spontaneously within 3 days. The area of local tissue reaction is in general below 2 cm in diameter. Anaphylactic-type reactions (vomiting, tremors and/or mild depression) may uncommonly occur in piglets shortly after vaccination. These resolve without treatment within few hours.

A minor and transient increase in rectal temperature (0.2 °C on average, and up to 1.0 °C individually) may very commonly occur 4 hours post vaccination in pre-breeding PRRS virus-naïve gilts and sows. Local reactions in the form of swellings are very common and resolve spontaneously within 5 days. The area of local tissue reaction is in general below 0.5 cm in diameter.

A minor and transient increase in rectal temperature (0.8 °C on average, and up to 1.0 °C individually) may very commonly occur 4 hours post vaccination in PRRS virus-naïve gilts and sows in the first half of pregnancy. Local reactions in the form of swellings are very common and resolve spontaneously within 9 days. The area of local tissue reaction is in general below 1.4 cm in diameter.

A minor and transient increase in rectal temperature (0.4 °C on average, and up to 0.6 °C individually) may very commonly occur 4 hours post vaccination in non-PRRS virus-naïve gilts and sows in the second half of pregnancy. Local reactions in the form of swellings are very common and resolve spontaneously within 32 days. The area of local tissue reaction is in general below 5 cm in diameter.

The frequency of possible adverse effects is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (pigs for fattening, gilts and sows).

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

Intramuscular injection: 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 intramuscularly.

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 intramuscularly 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. 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.

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 PERIOD(S)

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 vial after EXP.

Shelf life after reconstitution: use immediately.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

Special warnings for use in animals:
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.
Animals vaccinated via intramuscular route may excrete the vaccine strain for more than 16 weeks following vaccination. Animals vaccinated via nasal route may excrete the vaccine strain for more than 10 weeks following vaccination 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:
The safety of the vaccine has not been established 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 (symptoms, emergency procedures, 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 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 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-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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. 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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. 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.

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.