ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20 ml, 100 ml and 200 ml vaccine
(10/50/100 dose units: lyophilisate + solvent in one single outer package)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU Lyophilisate and Solvent for Suspension for Injection for Pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Live attenuated Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), strain 94881 (genotype 1): $10^{3.9}$-$10^{7.0}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

1 x 10 doses (lyophilisate) and 1 x 20 ml (solvent)
1 x 50 doses (lyophilisate) and 1 x 100 ml (solvent)
1 x 100 doses (lyophilisate) and 1 x 200 ml (solvent)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP{month/year}
Once reconstituted, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIFIC 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, IF APPLICABLE

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4301

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

12x10/12x50/12x100 dose units: only lyophilisates
25x10/25x50/25x100 dose units: only lyophilisates

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU lyophilisate for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Live attenuated Porcine Reproductive and Respiratory Syndrome virus (PRRSV), strain 94881 (genotype 1): $10^{3.9}$-$10^{7.0}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate

4. PACKAGE SIZE

12 x 20 ml (10 doses)
12 x 100 ml (50 doses)
12 x 200 ml (100 doses)
25 x 20 ml (10 doses)
25 x 100 ml (50 doses)
25 x 200 ml (100 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP{month/year}
Once reconstituted, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIFIC 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, IF APPLICABLE

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4301

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

12x10/12x50/12x100 dose units: only solvent
25x10/25x50/25x100 dose units: only solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for ReproCyc PRRS EU

2. STATEMENT OF ACTIVE SUBSTANCES

Phosphate buffer solution
Carbomer: 2.0 mg

3. PHARMACEUTICAL FORM

Solvent

4. PACKAGE SIZE

12 x 20 ml
12 x 100 ml
12 x 200 ml
25 x 20 ml
25 x 100 ml
25 x 200 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP{month/year}
Once reconstituted, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIFIC 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, IF APPLICABLE

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4301

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 200 ml vaccine lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU lyophilisate for pigs

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each dose (2 ml) contains:
Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), strain 94881 (genotype 1)

3. PHARMACEUTICAL FORM

Lyophilisate

4. PACKAGE SIZE

100 ml (50 doses)
200 ml (100 doses)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once reconstituted, use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4301

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS -

20 ml vaccine lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU lyophilisate for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (2 ml) contains:
Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), strain 94881 (genotype 1)

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

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP{month/year}
Once reconstituted, use within 8 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING OF THE SOLVENT

20 ml, 100 ml and 200 ml solvent

1. NAME OF THE SOLVENT

Solvent for ReproCyc PRRS EU

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

20 ml
100 ml
200 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP{month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
ReproCyc PRRS EU 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 the batch release:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU 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:
Live attenuated Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), Strain 94881 (genotype 1): $10^{3.9}$-$10^{7.0}$ $TCID_{50}$*

* Tissue Culture Infectious Dose 50%

Adjuvant: Carbomer 2.0 mg

Lyophilisate: off-white to milky grey
Solvent: clear, colourless solution

4. INDICATIONS

For active immunisation of breeding females from farms affected with European (genotype 1) Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) to reduce the duration of viraemia, the proportion of viraemic gilts/sows and viral loads in blood after exposure to PRRSV as shown under experimental conditions.

Onset of immunity: 4 weeks
Duration of immunity: 17 weeks

Vaccination of breeding females according to the recommended schedule described in section “Dosage, route and method of administration” reduces the negative reproductive disorders associated with PRRSV.

Under experimental challenge conditions a reduction in transplacental virus transmission after challenge was additionally demonstrated. In piglets from vaccinated sows, a reduction in the negative impact of PRRS virus infection (mortality, clinical signs and weight gain) was also demonstrated during the first 20 days of life.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in boars producing semen for naïve herds, as PRRSV can be shed in semen.
Do not use in PRRS naïve herds in which the presence of the PRRSV has not been established using reliable diagnostic methods.

6. ADVERSE REACTIONS

A transient increase in body temperature (up to 2°C above the physiological range) commonly occurs up to 5 days post-vaccination. Temperatures return to the normal range without additional treatment, 1 to 4 days after the maximum temperature increase is observed.

Reduced appetite may be observed commonly after vaccination.

Very minimal swelling or redness of the skin at the injection site may be observed commonly. These reactions (up to 10.5 cm but typically < 2 cm in size) are transient and subside within a short time (maximum of 5 days but typically less than 2 days) without treatment.

Recumbency and accelerated breathing can be observed uncommonly on the day of vaccination. These signs disappear spontaneously without any treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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

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

Dosage and method of administration:
Single intramuscular injection of one dose (2 ml), irrespective of body weight.

For reconstitution, transfer the entire content of the solvent vial to the vial containing the lyophilisate and reconstitute the lyophilisate as follows: 10 doses in 20 ml, 50 doses in 100 ml and 100 doses in 200 ml of the solvent.
Ensure that the lyophilisate is completely reconstituted before use.
Visual appearance after reconstitution: clear, colourless suspension.

Regime of vaccination:
Gilts: for protection against PRRSV during pregnancy vaccination is recommended before integration into the sow herd between 2 and 5 weeks prior to breeding. Gilts can then be subjected to the same vaccination programme as the sow herd.
Sows: it is recommended to vaccinate pregnant and non-pregnant sows every 3 to 4 months.

Mixing with ReproCyc ParvoFLEX:
The full content of one vial of ReproCyc ParvoFLEX should be used to reconstitute the lyophilisate of one vial of ReproCyc PRRS EU. ReproCyc ParvoFLEX hereby replaces the solvent of ReproCyc PRRS EU.
Ensure that the lyophilisate is completely reconstituted before use.
Administer a single dose (2 ml) of the mixture intramuscularly.

The following corresponding presentations (doses) can be mixed:

ReproCyc PRRS EU (lyophilisate)	ReproCyc ParvoFLEX
10 doses	10 doses (20 ml)
50 doses	50 doses (100 ml)
100 doses	100 doses (200 ml)

The package leaflet of ReproCyc ParvoFLEX should also be consulted before the administration of the mixed product.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.
Use sterile equipment.
Avoid multiple broaching, for example by using automatic injectors.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 ˚C – 8 ˚C).
Do not freeze.
Protect from light.
Shelf life after reconstitution according to directions: 8 hours.
Shelf life after mixing with ReproCyc ParvoFLEX: 8 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species:
Vaccinate healthy animals only.
Precautions should be taken to avoid the transfer of the vaccine virus within the herd, e.g. from positive animals to naïve animals.

Special precautions for use in animals:
The vaccine strain can spread up to 5 weeks after vaccination to unvaccinated animals in contact but without any clinical consequence. Vaccinated animals may excrete the vaccine strain by faecal excretion. The potential excretion of the vaccine strain in the urine of vaccinated animals has not been investigated.

The vaccine strain has been detected in new-born piglets (blood, lung samples) when vaccinating naïve gilts during last third of gestation but without any clinical consequence.

Care should be taken to avoid spread of vaccine virus from vaccinated animals to unvaccinated animals that should remain free from PRRSV.

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

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.

Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd. A PRRS vaccine based on the same strain (strain 94881) and authorised for the immunisation of pigs from 17 days of age until the end of fattening and older can be used on the same farm.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case adverse reactions develop following accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.
PRRSV naïve gilts should not be vaccinated during pregnancy.

Interactions (with other medicinal products and other forms of interaction):
Safety and efficacy data are available which demonstrate that this vaccine can be mixed with ReproCyc ParvoFLEX or administered at one injection site.

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):
No adverse events other than those listed in section “Adverse Reactions” for a single dose were observed following a 10-fold overdose administration.

Incompatibilities:
Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product or ReproCyc ParvoFLEX.

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

January 2022

15. OTHER INFORMATION

Pack sizes:
Cardboard box of 1 lyophilisate vial of 20 ml and 1 solvent vial of 20 ml (10 doses).
Cardboard box of 1 lyophilisate vial of 100 ml and 1 solvent vial of 100 ml (50 doses).
Cardboard box of 1 lyophilisate vial of 200 ml and 1 solvent vial of 200 ml (100 doses).

Cardboard box of 12 lyophilisate vials of 20 ml (10 doses) and Cardboard box of 12 solvent vials of 20 ml (10 doses).
Cardboard box of 12 lyophilisate vials of 100 ml (50 doses) and Cardboard box of 12 solvent vials of 100 ml (50 doses).
Cardboard box of 12 lyophilisate vials of 200 ml (100 doses) and Cardboard box of 12 solvent vials of 200 ml (100 doses).
Cardboard box of 25 lyophilisate vials of 20 ml (10 doses) and Cardboard box of 25 solvent vials of 20 ml (10 doses).
Cardboard box of 25 lyophilisate vials of 100 ml (50 doses) and Cardboard box of 25 solvent vials of 100 ml (50 doses).
Cardboard box of 25 lyophilisate vials of 200 ml (100 doses) and Cardboard box of 25 solvent vials of 200 ml (100 doses).

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 02 March 2022