

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881,
live attenuated: $10^{3.9}$ - $10^{7.0}$ TCID₅₀

3. 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)

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted, use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER(S)

Vm 61700/5014

Vm 61700/3018

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 12x10/12x50/12x100 dose units: only lyophilisates vials
Cardboard box of 25x10/25x50/25x100 dose units: only lyophilisates vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU lyophilisate

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881,
live attenuated: $10^{3.9}$ - $10^{7.0}$ TCID₅₀

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp.{dd/mm/yyyy}
Once reconstituted, use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER(S)

Vm 61700/5014

Vm 61700/3018

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 12x10/12x50/12x100 dose units: only solvent vials
Cardboard box of 25x10/25x50/25x100 dose units: only solvent vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for ReproCyc PRRS EU

2. STATEMENT OF ACTIVE SUBSTANCES

3. 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

4. TARGET SPECIES

Pigs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp.{ mm/yyyy}
Once reconstituted, use within 8 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER(S)

Vm 61700/5014

Vm 61700/3018

15. 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

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 2 ml dose contains:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881,
live attenuated: $10^{3.9} - 10^{7.0}$ TCID₅₀

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

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

i.m. use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted, use within 8 hours.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. 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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 doses (20 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp.{dd/mm/yyyy}
Once reconstituted, use within 8 hours.

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. TARGET SPECIES

Pigs

20 ml

100 ml

200 ml

3. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

4. EXPIRY DATE

Exp.{mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 2 ml dose contains:

Active substance:

Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated: $10^{3.9}$ - $10^{7.0}$ TCID₅₀ *

* Tissue Culture Infectious Dose 50%

Adjuvant: Carbomer 2.0 mg

Lyophilisate: off-white to milky grey

Solvent: clear, colourless solution

3. Target species

Pigs.

4. Indications for use

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 cases 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. Special warnings

Special warnings:

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 safe use in the target species:

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 PRRS virus.

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 of accidental self-injection, seek medical advice immediately 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 and 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 except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

Overdose:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product or ReproCyc ParvoFLEX as mentioned in section “Interactions with other medicinal products and other forms of interaction” above.

7. Adverse events

Pigs:

Common (1 to 10 animals / 100 animals treated):

Injection site reaction (injection site swelling; injection site reddening)¹
Decreased appetite, elevated temperature²

Uncommon (1 to 10 animals / 1 000 animals treated):

Increased respiratory rate³, recumbency³

- ¹ Very minimal (up to 10.5 cm but typically < 2 cm in size), subside within a short time (maximum of 5 days but typically less than 2 days) without treatment.
- ² Increase up to 2°C above the physiological range 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.
- ³ On the day of vaccination and disappears spontaneously without any 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 or its local representative using the contact details at the end of this leaflet, or via your national reporting system:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>
e-mail: adverse.events@vmd.gov.uk

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

Intramuscular use (i.m.).

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.

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

Ensure that the lyophilisate is completely reconstituted before use.

Visual appearance after reconstitution: clear, colourless suspension.

Avoid introduction of contamination during use.

Use sterile equipment.

Avoid multiple broaching, for example by using automatic injectors.

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).

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 carton and label after Exp. The expiry date for solvent refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist 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

Vm 61700/5014

Vm 61700/3018

Cardboard box of 1 lyophilisate vial of 20 ml (10 doses), 100 ml (50 doses) or 200 ml (100 doses) and 1 solvent vial of 20 ml, 100 ml or 200 ml.

Cardboard box of either 12 or 25 lyophilisate vials of 20 ml (10 doses), 100 ml (50 doses) or 200 ml (100 doses).

Cardboard box of either 12 or 25 solvent vials of 20 ml, 100 ml or 200 ml.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany
+353 1 291 3985

Manufacturer responsible for the batch release:

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

17. Other information

The vaccine is designed to stimulate the development of an immune response in pigs to Porcine Reproductive and Respiratory Syndrome virus.

ReproCyc PRRS EU® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence.

POM-V

Gavin Hall
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