1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc PRRS EU lyophilisate and solvent for suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:
Lyophilisate:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated: $10^{3.9}$ -$10^{7.0}$ $TCID_{50}$ *
* Tissue Culture Infectious Dose 50%

Adjuvant:
Solvent:
Carbomer: 2.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sucrose
Gelatin
Potassium hydroxide
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Sodium chloride
Solvent:
Phosphate buffered solution
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate
Water for injections

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

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 4.9 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.

3.3 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 PRRSV has not been established using reliable diagnostic methods.

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The vaccine strain may 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.

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

3.6 Adverse events

Pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site reaction (injection site swelling; injection site reddening)[1] Decreased appetite, elevated temperature[2]
Uncommon (1 to 10 animals / 1 000 animals treated):	Increased respiratory rate[3], Recumbency[3]

[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation and lay

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

3.8 Interaction 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.

3.9 Administration routes and dosage

Intramuscular use.

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

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.

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

No adverse events other than those listed in section 3.6 for a single dose were observed following a 10-fold overdose administration.

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.

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AD03

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

5. PHARMACEUTICAL PARTICULARS

5.1 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 3.8 above.

5.2 Shelf life

Shelf life of the vaccine lyophilisate as packaged for sale:	2 years.
Shelf life of the solvent as packaged for sale:	3 years.
Shelf life after reconstitution according to directions:	8 hours.
Shelf life after mixing with ReproCyc ParvoFLEX:	8 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Lyophilisate:
Type I amber glass vials with bromobutyl rubber stopper and aluminium seal.

Solvent:
High density polyethylene (HDPE) vials with a bromo- or chlorobutyl rubber stopper and aluminium seal.

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 package 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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/012/001

8. DATE OF FIRST AUTHORISATION

02/04/2015

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

16/09/2025

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*).