SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

The name [the product] will be used in the Product Information

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substance
Lyophilisate:
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
Solvent:
Carbomer: 2.0 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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.

4.3 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 PRRSV has not been established using reliable diagnostic methods.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals
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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation and lay

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

4.8 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. 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

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.

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

No adverse events other than those listed in section 4.6 for a single dose were observed following a 10-fold overdose administration.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Suidae, live viral vaccines for pigs.
Porcine Reproductive and Respiratory Syndrome Virus
ATCvet code: QI09AD03

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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 injection
Carbomer

6.2 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.

6.3 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

6.4 Special precautions for storage

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

6.5 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 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 package sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4301

9. DATE OF AUTHORISATION

26 March 2015

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 02 March 2022