SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc ParvoFLEX suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substance:
Porcine Parvovirus strain 27a VP2 subunit antigen ≥ 1.0 RP*
* Relative Potency (ELISA)

Adjuvant:
Carbomer 2 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Water for injections
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate anhydrous

Suspension for injection.
Colourless to slightly brown, opalescent suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

For active immunisation of gilts and sows from the age of 5 months to protect progeny against transplacental infection caused by porcine parvovirus.

Onset of immunity: from the beginning of the gestational period.
Duration of immunity: 6 months

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]; Injection site reddening[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[2].

[1] Transient, up to 4 cm, resolve within two to five days without treatment.
[2] Body temperature resolve spontaneously within 24 to 48 hours.

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 or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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 PRRS EU 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

Shake well before use.
Avoid introduction of contamination during use.

Primary vaccination scheme:
For pigs previously non-vaccinated against porcine parvovirus:
Two intramuscular injections of one dose, 3 weeks apart.
The second dose being given at least 3 weeks before mating.

Re-vaccination scheme:
One intramuscular injection of one dose at least every 6 months is recommended in a whole herd programme (see section 3.2).

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

The package leaflet of ReproCyc PRRS EU should also be consulted before the administration of the mixed veterinary medicinal product.

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

No data available.

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: QI09AA02

This vaccine is designed to stimulate the development of an active immune response in pigs to porcine parvovirus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except with ReproCyc PRRS EU.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:	2 years
Shelf life after first opening the immediate packaging:	8 hours
Shelf life after mixing with ReproCyc PRRS EU:	8 hours

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene bottles containing 20 ml (10 doses), 100 ml (50 doses) and 200 ml (100 doses). Each bottle is closed with a rubber stopper and an aluminium cap.

1 bottle of 20 ml (10 doses), 100 ml (50 doses) or 200 ml (100 doses) packed in a cardboard box.
12 bottles of 20 ml (10 doses), 100 ml (50 doses) or 200 ml (100 doses) packed in a cardboard box.
Not all pack sizes may be marketed.

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

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 applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 04491/5057

8. DATE OF FIRST AUTHORISATION

22 May 2019

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

April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 11 August 2025