ANNEX I

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 substances:
Porcine Parvovirus, strain 27a, VP2 protein ≥ 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

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] Resolving within 2 to 5 days without treatment.
[2] Resolves 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 and administered with ReproCyc PRRS EU 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.

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.

Cardboard box with 1 bottle of 20 ml (10 doses), or 100 ml (50 doses), or 200 ml (100 doses).
Cardboard box with 12 bottles of 20 ml (12 x 10 doses), or 100 ml (12 x 50 doses), or 200 ml (12 x 100 doses).

Not all pack 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)

EU/2/19/237/001-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

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

MM/YYYY

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).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 20 ml, 100 ml, 200 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc ParvoFLEX suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Porcine Parvovirus, strain 27a, VP2 protein: ≥ 1.0 RP*
* Relative Potency (ELISA)

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well before use.
Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton in order to 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 NUMBERS

EU/2/19/237/001
EU/2/19/237/002
EU/2/19/237/003
EU/2/19/237/004
EU/2/19/237/005
EU/2/19/237/006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml, 200 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc ParvoFLEX suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Porcine Parvovirus, strain 27a, VP2 protein: ≥ 1.0 RP*
* Relative Potency (ELISA)

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

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
i.m.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

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

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Keep the bottle in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc ParvoFLEX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 ml (10 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ReproCyc ParvoFLEX suspension for injection for pigs

2. Composition

Each dose (2 ml) contains:

Active substances:
Porcine Parvovirus, strain 27a, VP2 protein: ≥ 1.0 RP*
* Relative potency (ELISA).

Adjuvant: Carbomer: 2 mg.

Colourless to slightly brown, opalescent suspension.

3. Target species

Pigs.

4. Indications for use

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

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with ReproCyc PRRS EU 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.

Major incompatibilities:

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

7. 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] Resolving within 2 to 5 days without treatment.
[2] Resolves spontaneously within 24 to 48 hours.

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: {national system details}.

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

Intramuscular 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 six months is recommended in a whole herd programme (see section “Indications for use”).

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.

9. Advice on correct administration

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

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.
Keep the bottle in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp.
Shelf life after first opening of the bottle: use within 8 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/19/237/001-006

1 bottle of 20 ml (10 doses), 100 ml (50 doses) or 200 ml (100 doses).
12 bottles of 20 ml (10 doses), 100 ml (50 doses) or 200 ml (100 doses).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein

Germany

Local representatives and contact details to report suspected adverse events:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
BE-1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

Република България
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
AT-1121 Виена, Австрия
Tel: +359 2 958 79 98

Česká republika
Boehringer Ingelheim spol. s r.o.
Purkyňova 2121/3
CZ - 110 00, Praha 1
Tel: +420 234 655 111

Danmark
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tlf: + 45 3915 8888

Deutschland
Boehringer Ingelheim Vetmedica GmbH
DE-55216 Ingelheim/Rhein
Tel: 0800 290 0 270

Eesti
Boehringer Ingelheim RCV GmbH & Co KG
Eesti filiaal
Dr. Boehringer Gasse 5-11
AT-1121 Viin, Austria
Tel: +372 612 8000

Ελλάδα
Boehringer Ingelheim Vetmedica GmbH
DE-55216 Ingelheim/Rhein, Γερμανία
Τηλ: +30 2108906300

España
Boehringer Ingelheim Animal Health España, S.A.U.
Prat de la Riba, 50
ES-08174 Sant Cugat del Vallès (Barcelona)

Lietuva
Boehringer Ingelheim RCV GmbH & Co KG
Lietuvos filialas
Dr. Boehringer Gasse 5-11
AT-1121 Viena, Austrija
Tel: +370 5 2595942

Luxembourg/Luxemburg
Boehringer Ingelheim Animal Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
BE-1050 Bruxelles/Brussel/Brüssel
Tél/Tel: + 32 2 773 34 56

Magyarország
Boehringer Ingelheim RCV GmbH & Co KG
Magyarországi Fióktelep
Lechner Ö. Fasor 10.
HU-1095 Budapest
Tel: +36 1 299 8900

Malta
Boehringer Ingelheim Vetmedica GmbH
DE-55216 Ingelheim/Rhein, il-Ġermanja
Tel: +353 1 291 3985

Nederland
Boehringer Ingelheim Animal Health Netherlands B.V.
Basisweg 10
NL-1043 AP Amsterdam
Tel: +31 20 799 6950

Norge
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 København S
Tlf: +47 66 85 05 70

Österreich
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
AT-1121 Wien
Tel: +43 1 80105-6880

Polska
Boehringer Ingelheim Sp. z o.o.
ul. Józefa Piusa Dziekońskiego 3
PL-00-728 Warszawa
Tel.: + 48 22 699 0 699

Tel: +34 93 404 51 00

France
Boehringer Ingelheim Animal Health France, SCS
29, avenue Tony Garnier
FR-69007 Lyon
Tél : +33 4 72 72 30 00

Hrvatska
Boehringer Ingelheim RCV GmbH & Co KG
Dr. Boehringer Gasse 5-11
AT-1121 Beč, Austrija
Tel: +385 1 2444 600

Ireland
Boehringer Ingelheim Vetmedica GmbH
DE-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

Ísland
Vistor
Hörgatún 2
IS-210 Garðabær
Sími: + 354 535 7000

Italia
Boehringer Ingelheim Animal Health Italia S.p.A.
Via Vezza d'Oglio, 3
IT-20139 Milano
Tel: +39 02 53551

Κύπρος
Boehringer Ingelheim Vetmedica GmbH
DE-55216 Ingelheim/Rhein, Γερμανία
Τηλ: +30 2108906300

Latvija
Boehringer Ingelheim RCV GmbH & Co KG
Latvijas filiāle
Dr. Boehringer Gasse 5-11
AT-1121 Vīne, Austrija
Tel: +371 67 240 011

Portugal
Boehringer Ingelheim Animal Health Portugal, Unipessoal, Lda.
Avenida de Pádua, 11
PT-1800-294 Lisboa
Tel: +351 21 313 5300

România
Boehringer Ingelheim RCV GmbH & Co KG
Sucursala Bucureşti
Dr. Boehringer Gasse 5-11
AT-1121 Viena, Austria
Tel: +40 21 302 28 00

Slovenija
Boehringer Ingelheim RCV GmbH & Co KG
Podružnica Ljubljana
Dr. Boehringer Gasse 5-11
AT-1121 Dunaj, Avstrija
Tel: +386 1 586 40 00

Slovenská republika
Boehringer Ingelheim RCV GmbH & Co KG, o.z.
Dr. Boehringer Gasse 5-11
AT-1121 Viedeň, Rakúsko
Tel: +421 2 5810 1211

Suomi/Finland
Vetcare Oy
PB 99
FI-24101 Salo
Puh/Tel: + 358 201443360

Sverige
Boehringer Ingelheim Animal Health Nordics A/S
Weidekampsgade 14
DK-2300 Köpenhamn S
Tel: +46 (0)40-23 34 00

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
DE-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

17. Other information

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