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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Transient redness or swelling (up to 4 cm) caused by the injection procedure is very common. Local reactions resolve within two to five days without treatment. An elevation in the body temperature after vaccination is common which resolves spontaneously within 24 to 48 hours.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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.

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 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.

4.9 Amounts to be administered and administration route

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:
injection of one dose at least every 6 months is

recommended in a whole herd programme (see section 4.2).

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 product.

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

No data available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated viral vaccines, porcine parvovirus ATCvet code: QI09AA02

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Sodium chloride
Water for injections
Potassium chloride

gen

phosphate Disodium
phosphate anhydrous

6.2 Major incompatibilities

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

6.3 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

6.4 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.

6.5 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.

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 Vetmedica GmbH 55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/237/001-006

9. DATE OF AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD.MM.YYYY

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.