

**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 VP2 subunit antigen: $\geq 1.0 \text{ RP}^*$

* 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.

i.m injection

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {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

Vm 04491/5057

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 VP2 subunit antigen: ≥ 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 injection

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {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



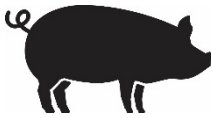
9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
20 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc ParvoFLEX



2. QUANTITATY OF PARTICULARS OF THE ACTIVE SUBSTANCES

20 ml (10 doses)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 8 hours.

PARTICULARS TO APPEAR ON THE 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 substance:

Porcine Parvovirus strain 27a VP2 subunit antigen: ≥ 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 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.

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 swelling¹

Injection site reddening¹

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Common (1 to 10 animals / 100 animals treated):

Elevated temperature²

¹ Transient, up to 4 com, resolving within 2 to 5 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 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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").

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.

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

Vm 04491/5057

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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim am Rhein
Germany

Local representatives and contact details to report suspected adverse reactions:

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue, Bracknell,
Berkshire,
RG12 8YS
United Kingdom
Tel: +44 1344746957

17. Other information

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

POM-V

Gavin Hall
Approved: 11 August 2025