ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance Boehringer Ingelheim Animal Health USA Inc.
2621 North Belt
Highway St. Joseph
Missouri, 64506-
2002 U.S.A.

Name and address of the manufacturers responsible for batch release Boehringer Ingelheim Vetmedica GmbH
55216
Ingelheim/Rhein
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not in the scope of Regulation (EC) 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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 for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:
Porcine Parvovirus VP2 subunit antigen: ≥ 1.0 RP*
* Relative Potency
(ELISA) Carbomer 2
mg.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZES

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)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Read the package leaflet
before use. Intramuscular
use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

16. MARKETING AUTHORISATION NUMBER

04491/5057

17. MANUFACTURER'S 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 for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:
Porcine Parvovirus VP2 subunit antigen: ≥ 1.0 RP*
* Relative Potency
(ELISA) Carbomer 2
mg.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet
before use. Intramuscular
use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Once broached use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH GERMANY

16. MARKETING AUTHORISATION NUMBER

04491/5057

17. MANUFACTURER'S BATCH NUMBER

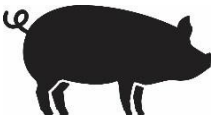
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc ParvoFLEX suspension for injection



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (2 ml): Porcine Parvovirus VP2
subunit antigen Carbomer

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml (10 doses)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 8 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
ReproCyc ParvoFLEX suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ReproCyc ParvoFLEX suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each dose (2 ml) contains:
Porcine Parvovirus strain 27a VP2 subunit antigen: ≥ 1.0 RP*
* Relative potency

(ELISA). Adjuvant:

Carbomer 2 mg.

Colourless to slightly brown, opalescent suspension for injection.

4. INDICATION(S)

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. ADVERSE REACTIONS

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 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 product.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

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 p rotect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after 'EXP'.

Shelf life after first opening of the bottle: use within 8 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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.

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

Interactions 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.

Overdose (symptoms, emergency procedures, antidotes):
No data available.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

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.

Approved 13 December 2023