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 manufacturer 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

10 ml, 50 ml, 100 ml, 250 ml vaccine bottles in a single cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (1 ml) contains: Porcine circovirus type 2 ORF2 protein
Carbomer

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZES

10 ml (10 doses)
50 ml (50 doses)
100 ml (100 doses)
250 ml (250 doses)
12 x 10 ml (12 x 10 doses)
12 x 50 ml (12 x 50 doses)
12 x 100 ml (12 x 100 doses)
12 x 250 ml (12 x 250 doses)

5. TARGET SPECIES

Pigs

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Shake well before use.
Single IM injection of 1 ml.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
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
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

16. MARKETING AUTHORISATION NUMBERS

Vm 04491/5013

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

https://youtu.be/xt9tJ8GRMXQ

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml, 250 ml vaccine bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (1 ml) contains: Porcine circovirus type 2 ORF2 protein
Carbomer

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZES

100 ml (100 doses)
250 ml (250 doses)

5. TARGET SPECIES

Pigs

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Shake well before use.
Single IM injection of 1 ml.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
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.

14. THE WORDS "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 NUMBERS

Vm 04491/5013

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml, 50 ml vaccine bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE

One dose (1 ml) contains: Porcine circovirus type 2 ORF2 protein
Carbomer

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

10 ml (10 doses)
50 ml (50 doses)

4. ROUTE OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Ingelvac CircoFLEX 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

Ingelvac CircoFLEX suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each dose (1 ml) contains:
Porcine circovirus type 2 ORF2 protein: RP* 1.0–3.75
* Relative potency (ELISA test) by comparison with a reference vaccine.

Adjuvant: Carbomer

Clear to slightly opalescent, colourless to yellowish suspension for injection.

4. INDICATIONS

For active immunisation of pigs from the age of 2 weeks against porcine circovirus type 2 (PCV2) to reduce mortality, clinical signs - including weight loss - and lesions in lymphoid tissues associated with PCV2 related diseases (PCVD).
In addition, vaccination has been shown to reduce PCV2 nasal shedding, viral load in blood and lymphoid tissues, and duration of viraemia.

Onset of immunity: 2 weeks post vaccination
Duration of immunity: at least 17 weeks.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A mild and transient hyperthermia very commonly occurs on the day of vaccination.
On very rare occasions anaphylactic reactions may occur and should be treated symptomatically.

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. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Pigs

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

Intramuscular use.
Single intramuscular (IM) injection of one dose (1 ml) to pigs, irrespective of body weight.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.
Avoid introduction of contamination during use.
Avoid multiple vial broaching.
Vaccination devices should be used in accordance with the device instructions provided by the manufacturer. After correct handling in accordance with the mixing instructions no leakage should occur. In case of any leakage or incorrect handling of the product the bottle should be discarded.

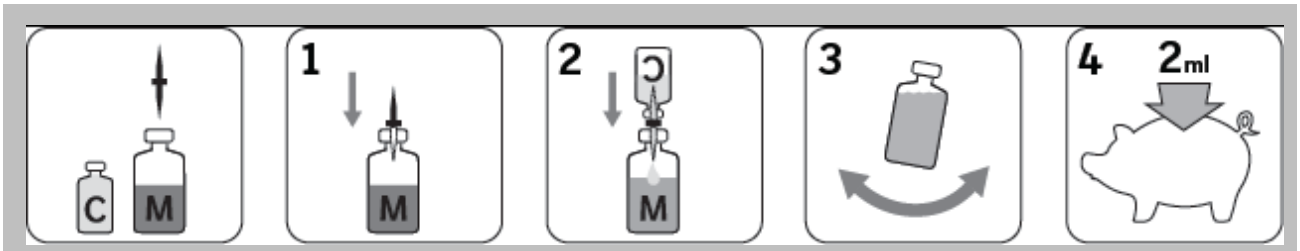
When mixed with Ingelvac MycoFLEX:
- Vaccinate only pigs as from 3 weeks of age.
- Cannot be administered in pregnant or lactating pigs.

When mixed with Ingelvac MycoFLEX the following equipment should be used:
- Use the same volumes of Ingelvac CircoFLEX and Ingelvac MycoFLEX.
- Use a pre-sterilised transfer needle. Pre-sterilised transfer needles (CE certified) are commonly available via medical equipment suppliers.

To ensure correct mixing follow the steps as described below:
1. Connect one end of the transfer needle to the vaccine bottle of Ingelvac MycoFLEX.
2. - Connect the opposite end of the transfer needle to the vaccine bottle of Ingelvac CircoFLEX.

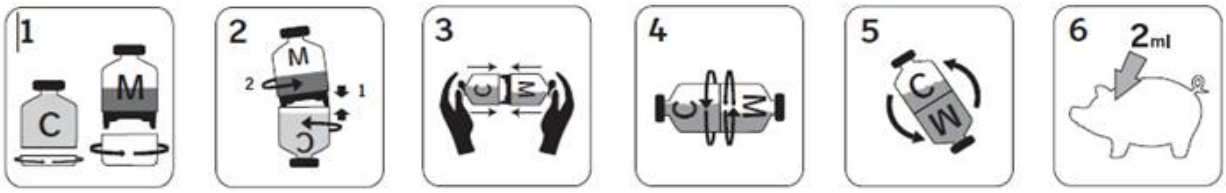
- Transfer the Ingelvac CircoFLEX vaccine into the vaccine bottle of Ingelvac MycoFLEX. If needed, gently press the vaccine bottle of Ingelvac CircoFLEX to facilitate the transfer.
- After the transfer of the full content of Ingelvac CircoFLEX, disconnect and discard transfer needle and empty vaccine bottle of Ingelvac CircoFLEX.

3. To ensure appropriate mixing of the vaccines, gently shake the vaccine bottle of Ingelvac MycoFLEX until the mixture is of uniform orange to reddish colour. During vaccination the uniformity of the coloured mixture should be monitored and maintained by continuous agitation.
4. Administer one single injection dose (**2 ml**) of the mixture intramuscularly per pig, irrespective of body weight. For administration, vaccine devices should be used in accordance with the device instructions provided by the manufacturer.



To ensure correct mixing with the TwistPak bottles follow the steps as described below or using the https://youtu.be/xt9tJ8GRMXQ

1. **Twist and remove** the red base of the bottle of Ingelvac MycoFLEX to uncover the connection system. The red base could be used upside down as a stand to position of the Ingelvac MycoFLEX bottle upside down.
   Twist and remove the green base of the Ingelvac CircoFLEX bottle.
2. **Rotate and align** the connection ends of the two bottles until they engage.
3. **Firmly push** the bottles together until they touch one another completely.
   A click confirms that the bottles are engaged.
4. **Twist** the two vaccine bottles clockwise to complete the coupling of both bottles.
5. To ensure appropriate mixing, slowly **invert** the locked bottles until the mixture is of uniform orange to reddish colour. During vaccination the uniformity of the coloured mixture should be monitored and maintained by continuous agitation.
6. Administer one single injection dose **(2 ml)** of the mixture intramuscularly per pig, irrespective of body weight. For administration, vaccine devices should be used in accordance with the device instructions provided by the manufacturer

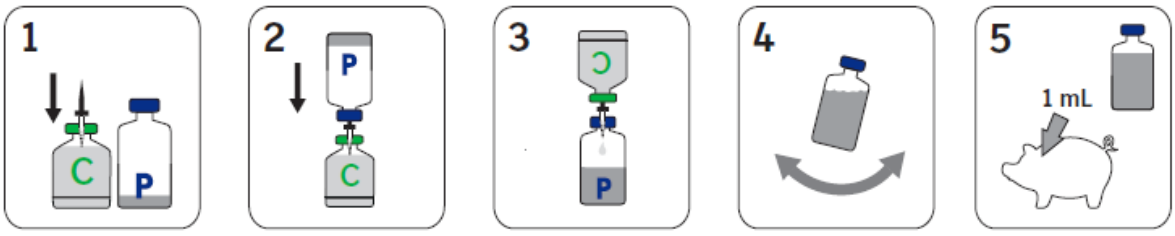


Use the entire vaccine mixture immediately after mixing. Any unused mixture or waste material should be disposed according with local requirements.

When mixed with Ingelvac PRRSFLEX EU:
- Vaccinate only pigs as from 17 days of age.
- Cannot be administered in pregnant or lactating pigs.

When mixed with Ingelvac PRRSFLEX EU the following equipment should be used:
- Use the same volumes of Ingelvac CircoFLEX and Ingelvac PRRSFLEX EU.
- Ingelvac CircoFLEX hereby replaces the solvent of PRRSFLEX EU
- Use a pre-sterilised transfer needle. Pre-sterilised transfer needles (CE certified) are commonly available via medical equipment suppliers.

To ensure correct mixing follow the steps as described below:
1. Connect one end of the transfer needle to the vaccine bottle of Ingelvac CircoFLEX.
2. Connect the opposite end of the transfer needle to the vaccine bottle of Ingelvac PRRSFLEX EU.
3. Transfer the Ingelvac CircoFLEX vaccine into the vaccine bottle of Ingelvac PRRSFLEX EU. If needed, gently press the vaccine bottle of Ingelvac CircoFLEX to facilitate the transfer.
   After the transfer of the full content of Ingelvac CircoFLEX, disconnect and discard transfer needle and empty vaccine bottle of Ingelvac CircoFLEX.
4. To ensure appropriate mixing of the vaccines, gently shake the vaccine bottle of Ingelvac PRRSFLEX until the cake is fully dissolved.
5. Administer one single injection dose (**1 ml**) of the mixture intramuscularly per pig, irrespective of body weight. For administration, vaccine devices should be used in accordance with the device instructions provided by the manufacturer.



Use the entire vaccine mixture within 4 hours after mixing. Any unused mixture or waste material should be disposed according to local requirements.

10. WITHDRAWAL PERIOD

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.
Protect 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 the bottle: use immediately.

12. SPECIAL WARNINGS

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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 either with Boehringer Ingelheim's Ingelvac MycoFLEX or Ingelvac PRRSFLEX EU and administered at one injection site. The product literature of Ingelvac MycoFLEX and Ingelvac PRRSFLEX EU should be consulted before administration.

After administration of Ingelvac CircoFLEX mixed with Ingelvac PRRSFLEX EU the following adverse reactions may occur: In individual pigs, the temperature increase after associated use rarely exceeds 1.5°C but stays below an increase of 2°C. The temperature returns to normal within 1 day after the peak temperature is observed. Transient local injection site reactions, which are restricted to a slight redness, may rarely occur directly after vaccination. Reactions resolve within 1 day. Immediate mild hypersensitivity-like reactions were commonly observed after vaccination, resulting in transient clinical signs such as vomiting and rapid respiration, which resolved within a few hours without treatment. Transient purple skin discoloration was uncommonly observed and resolved without treatment. Appropriate precautions to minimise handling stress during the administration of the product may lower the frequency of hypersensitivity-like reactions.

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)
Following the administration of a 4-fold overdose of vaccine no adverse reactions other than those described under section “Adverse reactions” have been observed.

Incompatibilities
Do not mix with any other veterinary medicinal product, except with Boehringer Ingelheim´s Ingelvac MycoFLEX or Ingelvac PRRSFLEX EU (both mixtures not for use in pregnant or lactating pigs).

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

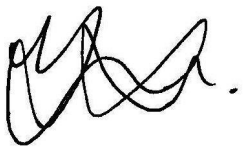
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

This vaccine is designed to stimulate the development of an active immune response to porcine circovirus type 2.

Pack sizes of 1 or 12 high density polyethylene or TwistPak bottles of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses). Not all pack sizes may be marketed.

Ingelvac MycoFLEX may be not authorised to use in certain Member States.
Ingelvac PRRSFLEX EU may be not authorised to use in certain Member States.



Approved: 23 May 2022