ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:
Active substance:
Porcine circovirus type 2 ORF2 capsid protein: RP* 1.0–3.75

* Relative potency (ELISA test) by comparison with a reference vaccine

Adjuvant:
Carbomer: 1 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Water for injections

Clear to slightly opalescent, colourless to yellowish suspension

3. CLINICAL INFORMATION

3.1 Target species

Pigs

3.2 Indications for use for each target species

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 disease (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.

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:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Pigs

Very common (> 1 animal / 10 animals treated):	Elevated temperature[1]
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Anaphylaxis[2]

1 Mild and transient on the day of vaccination.
2 Should be treated symptomatically.

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

After administration of Ingelvac CircoFLEX mixed with Ingelvac PRRSFLEX EU the following adverse events 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.

3.9 Administration routes and dosage

Intramuscular use.

Single intramuscular injection of one dose (1 ml), irrespective of body weight.

Shake well before use.

Avoid introduction of contamination during use.

Vaccines 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. Avoid multiple broaching.

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:
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 <u>two</u> vaccine bottles clockwise to complete the coupling of <u>both</u> 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 to the instructions given in section 5.5.

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 Ingelvac 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 the instructions given in section 5.5.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of a 4-fold overdose of vaccine no adverse events other than those described under section 3.6 have been observed.

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

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AA07

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major 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).

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: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C–8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box of either 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).
Each bottle is closed with a chlorobutyl stopper and lacquered aluminium seal.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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/2/07/079/001-008
EU/2/07/079/009-016 (TwistPak)

8. DATE OF FIRST AUTHORISATION

13/02/2008

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

{DD/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 REQIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 10 ml, 50 ml, 100 ml, 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml: Porcine circovirus type 2 ORF2 capsid protein

3. PACKAGE SIZE

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)

4. TARGET SPECIES

Pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well before use.
Single intramuscular injection.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
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/2/07/079/001 10 ml
EU/2/07/079/002 50 ml
EU/2/07/079/003 100 ml
EU/2/07/079/004 250 ml
EU/2/07/079/005 12 x 10 ml
EU/2/07/079/006 12 x 50 ml
EU/2/07/079/007 12 x 100 ml
EU/2/07/079/008 12 x 250 ml
EU/2/07/079/009 10 ml (TwistPak)
EU/2/07/079/010 50 ml (TwistPak)
EU/2/07/079/011 100 ml (TwistPak)
EU/2/07/079/012 250 ml (TwistPak)
EU/2/07/079/013 12 x 10 ml (TwistPak)
EU/2/07/079/014 12 x 50 ml (TwistPak)
EU/2/07/079/015 12 x 100 ml (TwistPak)
EU/2/07/079/016 12 x 250 ml (TwistPak)

15. BATCH NUMBER

Lot {number}
info.ingelvac-CircoFLEX.com/EU

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

Each dose of 1 ml: Porcine circovirus type 2 ORF2 capsid protein

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

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Shake well before use.
Single i.m. injection.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
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

10 ml, 50 ml vaccine bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ingelvac CircoFLEX suspension for injection for pigs

2. Composition

Each dose of 1 ml contains:
Active substance:
Porcine circovirus type 2 ORF2 capsid protein: RP* 1.0–3.75

* Relative potency (ELISA test) by comparison with a reference vaccine.

Adjuvant: Carbomer: 1 mg

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

3. Target species

Pigs

4. Indications for use

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. Special warnings

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.

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

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State’s competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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.

Major 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).

7. Adverse events

Pigs

Very common: (> 1 animal / 10 animals treated):
Elevated temperature[1]

Very rare: (< 1 animal / 10 000 animals treated, including isolated reports):
Anaphylaxis[2]

[1] Mild and transient on the day of vaccination.
[2] Should be treated symptomatically.

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

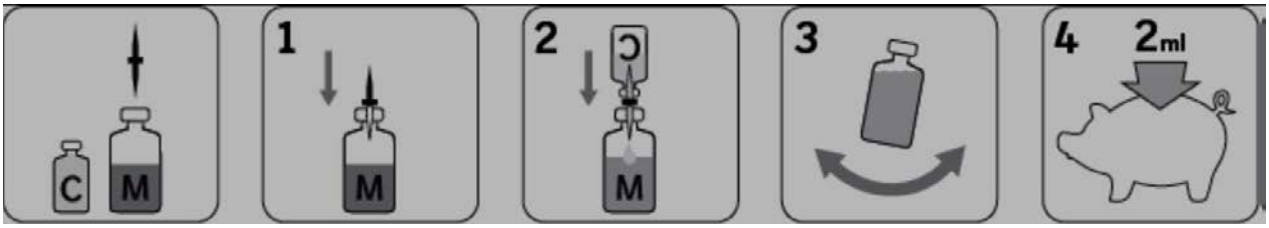
9. Advice on correct administration

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.

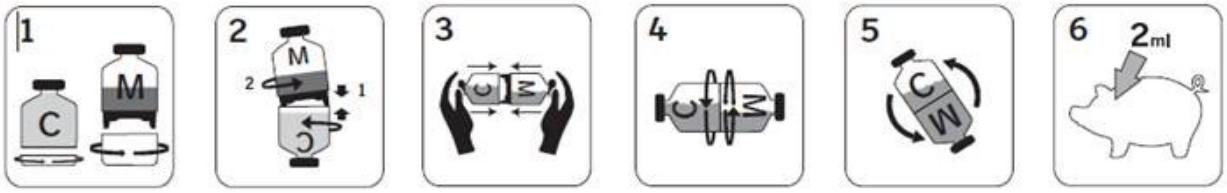
When mixed with Ingelvac MycoFLEX the following equipment should be used:
- Use the same volumes of Ingelvac CircoFLEX and Ingelvac MycoFLEX.
- Use a pre-sterilised transfer needle. Pre-sterilised transfer needles (CE certified) are commonly available via medical equipment suppliers.

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 info.ingelvac-CircoFLEX.com/EU

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.

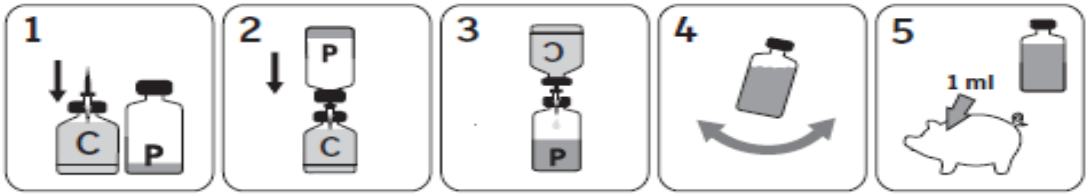


Use the entire mixture immediately after mixing. Any unused mixture or waste material should be disposed according with local requirements.

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 Ingelvac 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 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.
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 precautions for disposal

Medicines should not be disposed 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/2/07/079/001-008
EU/2/07/079/009-016 (TwistPak)

Cardboard box of either 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.

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

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

España
Boehringer Ingelheim Animal Health España, S.A.U.
Prat de la Riba, 50
ES-08174 Sant Cugat del Vallès (Barcelona)
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 Viena, Austrija
Tel: +371 67 240 011

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

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
PL/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 to porcine circovirus type 2.