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

Vm 61700/5051

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE Bottle label 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

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

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

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

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 Bottle label 10 ml, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once broached use immediately.

PARTICULARS TO APPEAR ON THE 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:

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

9. Advice on correct administration

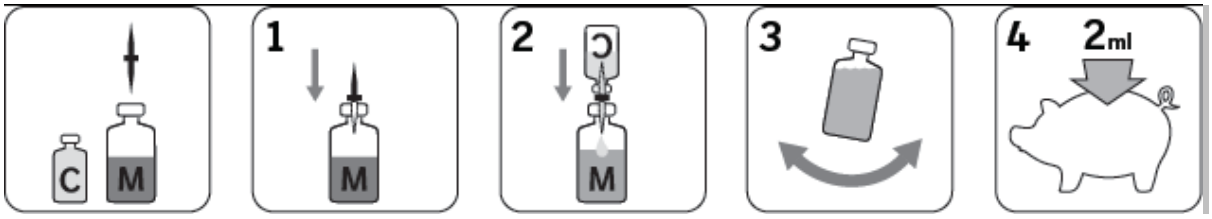
Shake well before use.
Avoid introduction of contamination during use.
Avoid multiple vial broaching.
Vaccination devices should be used in accordance with the device instructions provided by the manufacturer. After correct handling in accordance with the mixing instructions no leakage should occur.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

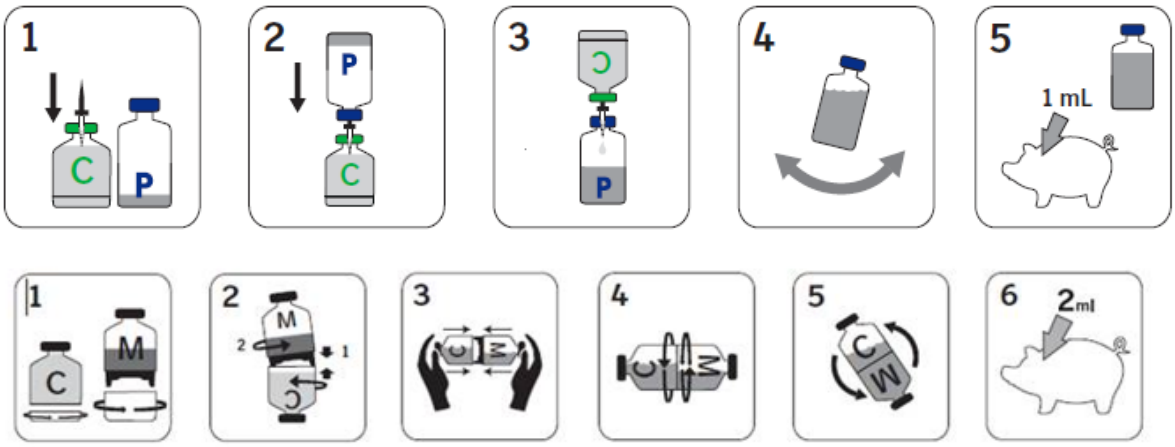
To ensure correct mixing follow the steps as described below:

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
https://www.vmd.defra.gov.uk/ProductInformationDatabase/product/A007012

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 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 61700/5051

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. 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
Binger Strasse 173
55216 Ingelheim am Rhein

Germany

Local representative and contact details to report suspected adverse reactions:

Boehringer Ingelheim Animal Health UK Limited
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 to porcine circovirus type 2.

POM-V

Gavin Hall

Approved: 10 December 2025