1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac CircoFLEX suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substance:
Porcine circovirus type 2 ORF2 protein RP* 1.0–3.75

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

Adjuvant:
Carbomer 1 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

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 reaction(s))
- 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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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 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.

4.9 Amounts to be administered and administration route

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 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 to the instructions given in section 6.6.

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 the instructions given in section 6.6.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Following the administration of a 4-fold overdose of vaccine no adverse reactions other than those described under section 4.6 have been observed.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Suidae, inactivated viral vaccines for pigs
ATCvet code: QI09AA07

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer
Sodium chloride
Water for injections

6.2 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).

6.3 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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBERS

EU/2/07/079/001-008
EU/2/07/079/009-016 (TwistPak)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13.02.2008
Date of last renewal: 14.01.2013

10. DATE OF REVISION OF THE TEXT

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

PROHIBITION OF SALE, SUPPLY AND/OR 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 in certain Member States.
Ingelvac PRRSFLEX EU may be not authorised in certain Member States.