ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PCV FLEX 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

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 with no PCV2 maternally derived antibodies from the age of 2 weeks against porcine circovirus type 2 (PCV2).
Under experimental challenge conditions in which only seronegative animals were included, it was demonstrated that vaccination reduces mortality, clinical signs 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
Not applicable.

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 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).

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 Ingelvac MycoFLEX 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.

4.9 Amounts to be administered and administration route

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.
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 recommendation should be followed:
- Use the same volumes of Ingelvac PCV FLEX 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 PCV FLEX.
   - Transfer the Ingelvac PCV FLEX vaccine into the vaccine bottle of Ingelvac MycoFLEX. If needed, gently press the vaccine bottle of Ingelvac PCV FLEX to facilitate the transfer.
   - After the transfer of the full content of Ingelvac PCV FLEX, disconnect and discard transfer needle and empty vaccine bottle of Ingelvac PCV FLEX.

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.

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.

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(s)

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 Ingelvac MycoFLEX (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 bottles of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses)or 250 ml (250 doses).
Each vial 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 NUMBER(S)

EU/2/17/208/001-008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24/05/2017

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

Ingelvac MycoFLEX may be not authorised in certain Member States.

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

D. CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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 Vetmedica Inc.
2621 North Belt Highway,
St. Joseph,
Missouri, 64506
U.S.A.

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

Boehringer Ingelheim Animal Health Operations B.V.
C. J. van Houtenlaan 36
1381 CP Weesp
THE NETHERLANDS

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

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.

D. CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

The PSURs for Ingelvac PCV FLEX shall be submitted at the same frequency as for Ingelvac CircoFLEX.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 10 ml, 50 ml, 100 ml, 250 ml bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PCV FLEX suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Suspension for injection

4. 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)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Intramuscular 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

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
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/208/001 10 ml
EU/2/17/208/002 50 ml
EU/2/17/208/003 100 ml
EU/2/17/208/004 250 ml
EU/2/17/208/005 12 x 10 ml
EU/2/17/208/006 12 x 50 ml
EU/2/17/208/007 12 x 100 ml
EU/2/17/208/008 12 x 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml, 250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PCV FLEX suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular 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

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.

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(S)

EU/2/17/208/003 100 ml
EU/2/17/208/004 250 ml
EU/2/17/208/007 12 x 100 ml
EU/2/17/208/008 12 x 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

10 ml, 50 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PCV FLEX suspension for injection for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose (1 ml): 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(S) 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 PCV FLEX 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:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health Operations B.V.
C. J. van Houtenlaan 36
1381 CP Weesp
THE NETHERLANDS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PCV FLEX suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) 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 1 mg.

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

4. INDICATION(S)

For active immunisation of pigs with no PCV2 maternally derived antibodies from the age of 2 weeks against porcine circovirus type 2 (PCV2).
Under experimental challenge conditions in which only seronegative animals were included, it was demonstrated that vaccination reduces mortality, clinical signs 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.

7. TARGET SPECIES

Pigs

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

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

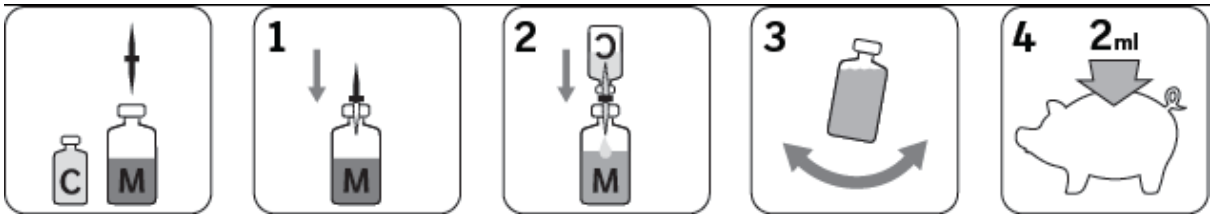
9. ADVICE ON CORRECT ADMINISTRATION

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.

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 recommendations should be followed:
- Use the same volumes of Ingelvac PCV FLEX 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 PCV FLEX.
   - Transfer the Ingelvac PCV FLEX vaccine into the vaccine bottle of Ingelvac MycoFLEX. If needed, gently press the vaccine bottle of Ingelvac PCV FLEX to facilitate the transfer.
   - After the transfer of the full content of Ingelvac PCV FLEX, disconnect and discard transfer needle and empty vaccine bottle of Ingelvac PCV FLEX.
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.



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

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.
Protect from light.
Do not use after the expiry date (EXP) which is stated on the carton and the bottle.
Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNING(S)

Vaccinate healthy animals only.

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 Ingelvac MycoFLEX 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)
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 Ingelvac MycoFLEX (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 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 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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.