ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 ml, 50 ml, 100 ml and 250 ml vaccine vials
(10/50/100/250 dose units: lyophilisate + solvent vials in one single cardboard box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Live attenuated Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), strain 94881 (genotype 1): $10^{4.4}$-$10^{6.6}$$TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

1 x 10 doses (lyophilisate) and 1 x 10 ml (solvent)
1 x 50 doses (lyophilisate) and 1 x 50 ml (solvent)
1 x 100 doses (lyophilisate) and 1 x 100 ml (solvent)
1 x 250 doses (lyophilisate) and 1 x 250 ml (solvent)

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP{month/year}
Once reconstituted use within 8 hours.

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 Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4297

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

12x10/12x50/12x100/12x250 dose units: only lyophilisates vials
25x10/25x50/25x100/25x250 dose units: only lyophilisates vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Live attenuated Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), strain 94881 (genotype 1): $10^{4.4}$-$10^{6.6}$ $TCID_{50}$

3. PHARMACEUTICAL FORM

Lyophilisate

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP{month/year}
Once reconstituted, use within 8 hours.

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 Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4297

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

12x10/12x50/12x100/12x250 dose units: only solvent vials
25x10/25x50/25x100/25x250 dose units: only solvent vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Ingelvac PRRSFLEX EU

2. STATEMENT OF ACTIVE SUBSTANCES

Phosphate buffered solution

3. PHARMACEUTICAL FORM

Solvent.

4. PACKAGE SIZE

12 x 10 ml
12 x 50 ml
12 x 100 ml
12 x 250 ml
25 x 10 ml
25 x 50 ml
25 x 100 ml
25 x 250 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

EXP{month/year}
Once reconstituted use within 8 hours.

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 Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4297

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml vaccine lyophilisate vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), strain 94881 (genotype 1)

3. PHARMACEUTICAL FORM

Lyophilisate

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
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIAL 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 Animal Health UK Ltd
Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4297

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS -

10 ml and 50 ml vaccine lyophilisate vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate for pigs

2. QUANTITY OF THE ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), strain 94881 (genotype 1)

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(s): Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP{month/year}
Once reconstituted use within 8 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

10 ml, 50 ml, 100 ml and 250 ml solvent vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Ingelvac PRRSFLEX EU

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

10 ml
50 ml
100 ml
250 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP{month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Ingelvac PRRSFLEX EU lyophilisate and solvent for 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 Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each dose (1 ml) contains:
Live attenuated Porcine Reproductive and Respiratory Syndrome Virus (PRRSV), Strain 94881 (genotype 1): $10^{4.4}$-$10^{6.6}$$TCID_{50}$*

*Tissue Culture Infectious Dose 50

Lyophilisate: off-white to milky-grey
Solvent: clear, colourless solution

4. INDICATIONS

For active immunisation of clinically healthy pigs from 17 days of age until the end of fattening and older from farms affected with European (genotype 1) Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) to reduce virus load in blood in seropositive animals under field conditions.

Under experimental challenge conditions in which only seronegative animals were included, it was demonstrated that vaccination reduces lung lesions, virus load in blood and lung tissues as well as negative effects of infection on daily weight gain. A significant reduction of the respiratory clinical signs could additionally be demonstrated at the onset of immunity.

Onset of immunity: 3 weeks
Duration of immunity: 26 weeks

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in breeding animals.
Do not use in PRRS naïve herds in which the presence of PRRSV has not been established
using reliable diagnostic methods.

6. ADVERSE REACTIONS

Slight transient increases (not greater than 1.5°C) in body temperature can be observed very commonly following vaccination. Temperatures return to normal without additional treatment, 1 to 3 days after the maximum temperature increase is observed.

Injection site reactions are uncommon. Transient minimal swelling or redness of the skin may be observed. These reactions disappear spontaneously without any additional treatment.

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).

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(S) AND METHOD OF ADMINISTRATION

Dosage and method of administration:
Intramuscular use.
Single intramuscular injection of one dose (1 ml), irrespective of body weight.
For reconstitution, transfer the entire content of the solvent vial to the vial containing the lyophilisate and reconstitute the lyophilisate as follows: 10 doses in 10 ml, 50 doses in 50 ml, 100 doses in 100 ml and 250 doses in 250 ml of the solvent.
Ensure that the lyophilisate is completely reconstituted before use.
Visual appearance after reconstitution: clear, colourless suspension.

9. ADVICE ON CORRECT ADMINISTRATION

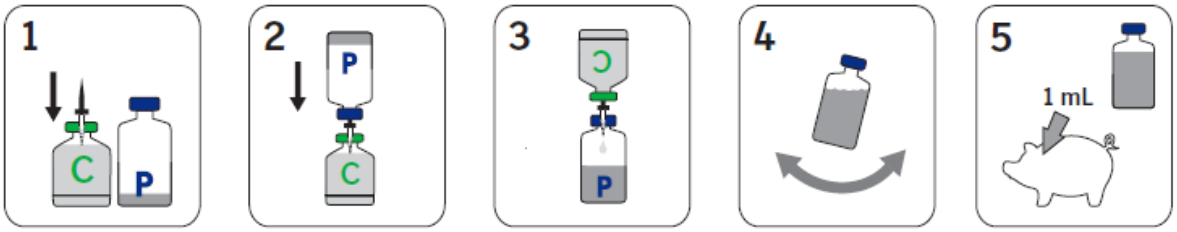
Avoid introduction of contamination during use.

Use sterile equipment.
Avoid multiple broaching, for example by using automatic injectors.

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

When mixed with Ingelvac CircoFLEX 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(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.
Shelf life after reconstitution with solvent according to directions: use within 8 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species:
Vaccinate healthy animals only.
Do not use in boars producing semen for naïve herds, as PRRSV can be shed in semen.
Maternally derived antibodies have been shown to interfere with vaccine efficacy. In the presence of maternally derived antibodies, timing of initial vaccination of piglets should be planned accordingly.

Special precautions for use in animals:
The vaccine strain can spread to unvaccinated animals in contact with vaccinated animals up to 3 weeks post vaccination. Special precautions should be taken to avoid spreading of the vaccine strain within the herd, e.g. from positive to naïve animals. Vaccinated animals may excrete the vaccine strain by faecal excretion and in some cases by oral secretions.

Care should be taken to avoid spread of vaccine virus from vaccinated animals to unvaccinated animals that should remain free from PRRS virus.

Vaccination should aim to achieve a homogenous immunity in the target population at farm level. In the sow herd it is recommended to use a vaccine strain licensed for use in sows.

Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd. A PRRS vaccine based on the same strain (strain 94881) and authorised for the immunisation of gilts and sows can be used on the same farm.

In order to limit the potential risk of recombination between PRRS MLV vaccine strains of the same genotype, do not use different PRRS MLV vaccines based on different strains of the same genotype on the same farm at the same time. In the case of transitioning from one PRRS MLV vaccine to another PRRS MLV vaccine, a transition period should be respected between the last administration of the current vaccine and the first administration of the new vaccine. This transition period should be longer than the shedding period of the current vaccine following vaccination.

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:
The safety of the veterinary medicinal product has not been established during pregnancy or 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 Boehringer Ingelheim's Ingelvac CircoFLEX and administered at one injection site.

The product literature of Ingelvac CircoFLEX should be consulted before administration. 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. 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):
No additional negative effects have been observed following the administration of a 10-fold overdose in naïve piglets of two weeks of age with regard to systemic and local reactions.

Incompatibilities:
Do not mix with any other veterinary medicinal product except solvent supplied for use with the veterinary medicinal product or Boehringer Ingelheim´s Ingelvac CircoFLEX (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

January 2022

15. OTHER INFORMATION

Pack sizes:
1 lyophilisate vial of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses) and 1 solvent vial of 10 ml, 50 ml, 100 ml or 250 ml packed in one cardboard box.

12 lyophilisate vials of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses) packed in a separate cardboard box.

25 lyophilisate vials of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses) packed in a separate cardboard box.

12 solvent vials of 10 ml, 50 ml, 100 ml or 250 ml packed in a separate cardboard box.

25 solvent vials of 10 ml, 50 ml, 100 ml or 250 ml packed in a separate cardboard box.

Not all pack sizes may be marketed.

Below information to be added only in case the MAH is not BIV GmbH: UK, FR
Ingelvac PRRSFLEX EU is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence.

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

Approved 02 March 2022