1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate and Ingelvac PRRSFLEX EU solvent for suspension for injection for pigs
(BE, CY, DE, EL, FR, IT, LU)

Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs
(AT, BG, CS, EE, ES, HR, HU, IE, LI, LT, LV, NL, PL, PT, RO, SI, SK, UK(NI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:
Lyophilisate:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated: $10^{4.4}$ - $10^{6.6}$ $TCID_{50}$*

* Tissue Culture Infectious Dose 50%

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sucrose
Gelatin
Potassium hydroxide
Glutamic acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Sodium chloride
Solvent:
Phosphate buffered solution
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium phosphate
Water for injections

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

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in 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.
Do not use in boars producing semen for naïve herds, as PRRSV can be shed in semen.

3.4 Special warnings

Vaccinate healthy animals only.
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.

3.5 Special precautions for use

Special precautions for safe use in the target species
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.

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]
Uncommon (1 to 10 animals / 1 000 animals treated):	Injection site reaction (injection site swelling, injection site reddening)[2]

[1] Slight increase not greater than 1.5 °C, return to normal without treatment, 1 to 3 days after the maximum temperature.
[2] Minimal, disappears spontaneously without treatment.

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 and lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or 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 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 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 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.
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 the instructions given in section 5.5.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AD03

The vaccine is designed to stimulate the development of an immune response in pigs to Porcine Reproductive and Respiratory Syndrome Virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major 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 as mentioned in section 3.8 above. Both mixtures are not for use in pregnant or lactating pigs..

5.2 Shelf life

Shelf life of the vaccine lyophilisate as packaged for sale:	2 years.
Shelf life of the solvent as packaged for sale:	3 years.
Shelf life after reconstitution with solvent according to directions:	8 hours.

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

Lyophilisate:
Type I amber glass vials with bromobutyl rubber stopper and aluminium seal.

Solvent:
High density polyethylene (HDPE) vials with bromo- or chlorobutyl rubber stopper and aluminium seal.

Cardboard box of 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.

Cardboard box of either 12 or 25 lyophilisate vials of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses).

Cardboard box of either 12 or 25 solvent vials of 10 ml, 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused 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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 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 1 ml dose contains:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated:
$10^{4.4}$-$10^{6.6}$$TCID_{50}$

3. 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)

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp.{dd/mm/yyyy}
Once reconstituted use within 8 hours.

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

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 12x10/12x50/12x100/12x250 dose units: only lyophilisates
Cardboard box of 25x10/25x50/25x100/25x250 dose units: only lyophilisates

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate for pigs

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml dose contains:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated:
$10^{4.4}$-$10^{6.6}$ $TCID_{50}$

3. PACKAGE SIZE

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

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp.{dd/mm/yyyy}
Once reconstituted, use within 8 hours.

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

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 12x10/12x50/12x100/12x250 dose units: only solvent vials
Cardboard box of 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. 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

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp.{mm/yyyy}
Once reconstituted use within 8 hours.

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 NUMBER(S)

15. 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 1 ml dose contains:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated:
$10^{4.4}$ - $10^{6.6}$ $TCID_{50}$

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

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

i.m. use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted use within 8 hours.

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 and 50 ml vaccine lyophilisate vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ingelvac PRRSFLEX EU lyophilisate

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 doses
50 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp.{dd/mm/yyyy}
Once reconstituted use within 8 hours.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS OF THE SOLVENT

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

1. NAME OF THE SOLVENT

Solvent for Ingelvac PRRSFLEX EU for pigs

2. TARGET SPECIES

Pigs

10 ml
50 ml
100 ml
250 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. EXPIRY DATE

Exp.{mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

7. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 1 ml dose contains:
Active substance:
Porcine Reproductive and Respiratory Syndrome Virus, type 1, strain PRRS 94881, live attenuated:
$10^{4.4}$ -$10^{6.6}$ $TCID_{50}$*
*Tissue Culture Infectious Dose 50

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

3. Target species

Pigs.

4. Indications for use

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 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.
Do not use in boars producing semen for naïve herds, as PRRSV can be shed in semen.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
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 safe use in the target species:
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 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:
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.

Major 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 as mentioned in section "Interactions with other medicinal products and other forms of interaction" above. Both mixtures are not for use in pregnant or lactating pigs.

7. Adverse events

Pigs:

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

Uncommon (1 to 10 animals /1 000 animals treated):
Injection site reaction (injection site swelling, injection site reddening)[2]

[1] Slight increase not greater than 1.5 °C, return to normal without treatment, 1 to 3 days after the maximum temperature.
[2] Minimal, disappear spontaneously without treatment.

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 (**i.m.**).

Single 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.

9. Advice on correct administration

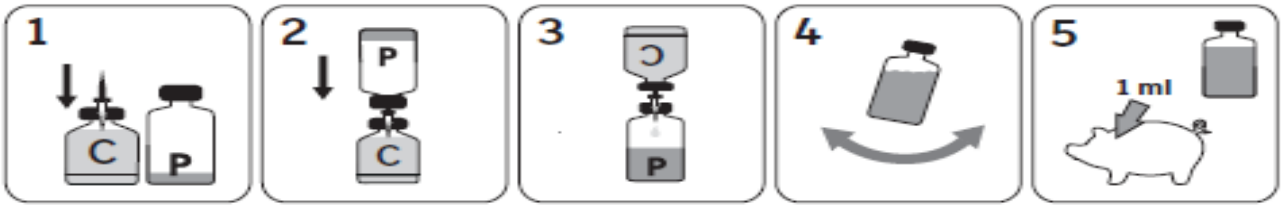
Ensure that the lyophilisate is completely reconstituted before use.
Visual appearance after reconstitution: clear, colourless suspension.
Avoid introduction of contamination during use.
Use sterile equipment.
Avoid multiple broaching, for example by using automatic injectors.

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 the instructions given in section “Special precautions for disposal”.

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.
Shelf life after reconstitution with solvent according to directions: 8 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after Exp.

12. Special precautions for disposal

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. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{DD/MM/YYYY)

Cardboard box of 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.

Cardboard box of either 12 or 25 lyophilisate vials of 10 ml (10 doses), 50 ml (50 doses), 100 ml (100 doses) or 250 ml (250 doses).

Cardboard box of either 12 or 25 solvent vials of 10 ml, 50 ml, 100 ml or 250 ml.
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:

17. Other information

The vaccine is designed to stimulate the development of an immune response in pigs to Porcine Reproductive and Respiratory Syndrome Virus).